

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FT. MYERS DIVISION

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

CELLMARK BIOPHARMA, LLC, a limited liability company; and

DEREK E. VEST, individually and as the owner of CellMark Biopharma, LLC,

Defendants.

Case No. _____

**COMPLAINT FOR PERMANENT
INJUNCTION AND OTHER
EQUITABLE RELIEF**

Plaintiff, the Federal Trade Commission (“FTC”), for its Complaint alleges:

1. The FTC brings this action under Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 53(b), to obtain permanent injunctive relief, rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for Defendants’ acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the advertising, marketing, promotion, offering for sale, sale, or distribution of CellAssure and Cognify, health products marketed to cancer patients experiencing malnutrition and cognitive dysfunction.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345, and 15 U.S.C. §§ 45(a) and 53(b).

3. Venue is proper in this district under 28 U.S.C. § 1391(b)(1), (b)(2), (c)(1), (c)(2), and (d), and 15 U.S.C. § 53(b).

PLAINTIFF

4. The FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The FTC also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce.

5. The FTC is authorized to initiate federal district court proceedings, by its own attorneys, to enjoin violations of the FTC Act and to secure such equitable relief as may be appropriate in each case, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies. 15 U.S.C. §§ 53(b) and 56(a)(2)(A).

DEFENDANTS

6. Defendant CellMark Biopharma, LLC (“CellMark”) is a Delaware limited liability company with its principal place of business at 1591 Hayley Ln., Suite 201, Fort Myers, FL 33907. CellMark transacts or has transacted business in this district and throughout the United States. At times material to this Complaint, acting alone or in concert with others,

CellMark advertised, marketed, distributed, or sold CellAssure and Cognify to consumers throughout the United States.

7. Defendant Derek E. Vest (“Vest”) is the founder and sole owner of CellMark. He is the Chairman of CellMark’s Board of Directors and has served as the Chief Executive Officer of CellMark. At times material to this Complaint, acting alone or in concert with others, he formulated, directed, controlled, had the authority to control, or participated in the acts and practices set forth in this Complaint. Defendant Vest resides in this district and, in connection with the matters alleged herein, transacts or has transacted business in this district and throughout the United States.

COMMERCE

8. At all times material to this Complaint, Defendants have maintained a substantial course of trade in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANTS’ BUSINESS ACTIVITIES

9. From January 2016 through approximately January 2017, CellMark sold two products, CellAssure and Cognify.

10. CellAssure is a powdered drink mix for cancer patients experiencing malnutrition, including cachexia, a wasting syndrome. Cognify is a supplement for cancer patients suffering from cognitive dysfunction caused by cancer treatment, including Mild Cognitive Impairment. CellMark charged \$248 and \$79 for a one-month supply of CellAssure and Cognify, respectively.

11. CellMark promoted, advertised, or sold CellAssure and Cognify, including through CellMark's website at www.cellmarkbiopharma.com. On its website, CellMark described CellAssure as a medical breakthrough solution with "anti-cancer and anti-tumor properties" for cancer patients suffering from cachexia, a wasting syndrome characterized by muscle loss, loss of appetite, nausea, and diarrhea; other cancer-related malnutrition; and the side effects of cancer treatments. CellMark described Cognify as a medical breakthrough solution for cancer patients suffering from cognitive dysfunction caused by chemotherapy, including Mild Cognitive Impairment ("chemo brain").

12. Defendant Vest exercised final decision-making authority over all aspects of CellMark's business. He played a key role in developing the formulation of CellAssure and Cognify, and in approving the manufacture, packaging, and labeling of CellAssure and Cognify. He developed advertising for CellAssure and Cognify, and registered CellMark's website, www.cellmarkbiopharma.com. Defendant Vest participated in reviewing substantiation for representations made in advertisements or promotional materials for CellAssure and Cognify. Defendant Vest approved all advertising claims disseminated to the public.

13. To induce consumers to purchase CellAssure and Cognify, Defendants disseminated or caused to be disseminated advertisements for CellAssure and Cognify, including but not necessarily limited to the attached Exhibits 1 through 4-B. These advertisements contain the following statements and depictions, among others:

A. CellAssure

1. Excerpts from www.cellmarkbiopharma.com (attached as Exhibit 1)



ADVANCED MEDICAL NUTRITION
FOR ALL CANCER PATIENTS

... **CellAssure**TM is an innovative **medical nutrition drink** designed for the needs of all cancer patients battling the detrimental effects of cancer and cancer treatments (surgery, radiation, chemotherapy and emotional turmoil).

(Exh. 1 at 1)

What is Medical Nutrition?

Medical Nutrition is a therapeutic composition formulated to meet the nutritional needs of patients with specific medical conditions in a manner that supports their physical sustenance, treatment protocol, and symptom management. Unlike general nutritional supplements, *Medical Nutrition* products are composed of ingredients clinically proven to improve the treatment of and recovery from specific conditions and are therefore utilized as part of the treatment plan for specific diagnoses under the supervision of an accredited healthcare provider, a registered dietitian, or professional nutritionist.

(Exh. 1 at 3)

CellAssure's clinically proven ingredients were scientifically formulated to deliver an unheard of level of health, protection and quality of life for our patients.

(Exh. 1 at 4)

CellAssure includes ingredients clinically proven to:

- Exhibit anti-cancer and anti-tumor properties
- Improve immune system response
- Maintain or increase appetite
- Increase LBM (lean body mass)
- . . .
- Provide relief with nausea/vomiting and diarrhea

(Exh. 1 at 4)

Why is CellAssure essential from your Day of Diagnosis?

With figures showing as much as 40% of cancer deaths are from malnutrition (cancer cachexia), the medical community agrees that nutritional intervention is imperative. Cachexia is a series of metabolic changes in the cancer patient's body. Cachexia is initiated when proinflammatory cytokines and other catabolic factors, such as proteolysis-inducing factor and lipid-mobilizing factor are released in tissues and in circulation. Increases in stress, anxiety, cortisol levels, inflammation and decreases in appetite, nutrient absorption, and liver function add to this hypermetabolic scenario.

“Cancer weight loss is associated with poor outcomes for cancer patients — reduced response to therapy, reduced ability to deliver full doses of chemotherapy, stoppages of cancer therapies, increased toxicity, more complications and infections, lower quality of life, and reduced survival.”

Cancer cachexia is far more complex and different than other types of weight loss (malnutrition or starvation) and it cannot be reversed by the simple addition of extra calories. CellAssure is targeted medical nutrition for these specific inflammatory triggers and all their resultant metabolic abnormalities!

(Exh. 1 at 5)

CellAssure – Fueling The Fight Against Cancer

CellAssure delivers We need a reason to believe that we can overcome, conquer and beat cancer head on.

(Exh. 1 at 6)

CellMark Biopharma™ is the leader in advanced medical nutrition for all cancer patients looking for the highest level of proven active ingredients to fuel their fight against cancer in one easy solution. . . .

(Exh. 1 at 6)

2. **Excerpt from CellMark YouTube channel profile page (attached at Exhibit 2)**

CellAssure specifically addresses the malnutrition suffered by over 80% of all cancer patients by providing one of the most advanced nutritional formulas for ones [sic] cancer diet than has been available in the past.

3. **Excerpts from Southwest Florida’s Health & Wellness Magazine, February 2016, CellAssure ad (attached as Exhibit 3)**



- **Demonstrates Anti-Cancer/Anti-tumor effects**

- **Promote a healthy immune response**
- **Preserve strength, stamina and appetite**
- **Stress and anxiety support**
- **Support and maintain lean body mass**
- **Help for nausea and diarrhea**

(Exh. 3 at 2)

Cancer Nutrition Drink is a Must Have

By Dr. Stan Headley

20-40% of cancer patients actually die from malnutrition (cachexia) and not cancer itself!

* * *

CellAssure is a simple once a day drink created from direct requests by physicians, dietitians, and patients battling cancer. CellAssure includes ingredients clinically proven to:

- Demonstrate Anti-Cancer/Anti-tumor effects
- Provide needed nutrition for cancer patients with zero sugar in formula

* * *

- Maintain or increase appetite
- Increase LBM (lean body mass)

* * *

- Provide relief [from] nausea/vomiting and diarrhea

* * *

CellAssure gives patients the essential daily medical nutrition needed to maintain their bodyweight [sic] and allow their body to better withstand the rigors of cancer treatments. Remember – staying as healthy as possible allows you to fight cancer without having to stop critical oncology therapies and protocols.

(Exh. 3 at 3)

B. **Cognify**

1. **Excerpts from www.cellmarkbiopharma.com (attached as Exhibit 1)**

Chemo brain is a common term used by cancer patients . . . to describe thinking, memory and concentration problems that can occur during, and after, cancer treatment. Chemo brain can also be called chemo fog, Mild Cognitive Impairment (MCI), or chemotherapy-related cognitive dysfunction.

Cognify™ is the world's first product designed specifically to alleviate chemo brain (chemo fog) signs and symptoms. Our patent pending formulation enhances neurocognitive functioning while providing enhanced neuroprotection. . . .

Cognify™: The Natural Solution to Chemo Brain

- **Neuroprotection** - protect brain cells/neuro-transmitters against toxins
- **Cognitive Enhancement** - increase cognitive processing and work efficiency
- **Increase Blood Flow** - increase blood flow, nutrients and oxygen to the brain
- **Repair Brain Tissue** - maintain brain cell membranes, repair brain cells & neurons
- **Reduce Inflammation** - decrease inflammation, oxidative stress and inflammatory cytokines
- **Increase Neurotransmitters** - improve cognitive functioning, memory, and processing
- **Promote Neurogenesis** - stimulate the growth of new brain cells

(Exh. 1 at 7-8)



What are some of the clinically proven ingredients in Cognify™?

Alpha-GPC

Choline-CDP

L-Theanine

Vinpocetine

When & how should my patients take Cognify™ to be most effective?

Cognify™ works on many pathways to help prevent chemo-brain [sic] with its clinically proven neuroprotective active ingredients. Although Cognify™ has been shown to help patients already experiencing “chemo brain” or cognitive decline due to cancer/cancer treatments, it is far more desirable to take Cognify™ prophylactically prior to chemotherapy. This proactive approach will provide you [sic] patient with the ability to deploy the neuroprotective components of our medical nutritional formula and aid in prevention of chemo-brain [sic].

(Exh. 1 at 9)

2. Excerpt from CellMark YouTube channel profile page (attached at Exhibit 2)

Cognify is the first nutritional supplement specifically formulated to protect against and /or help reduce brain fog (a|k|a [sic] chemo brain) associated with cancer and cancer treatments such as chemo therapy.

3. Excerpt from Cognify Video, Breast Cancer Survivor Talks About Cognify and Brain Fog (video attached as Exhibit 4-A and transcript attached as Exhibit 4-B)

SUE HABERKORN: Hi, I'm Sue, a recent breast cancer survivor. While I was on chemo, I noticed that I was having much more difficulty remembering ordinary objects and names of people. I was having a real brain fog, worse than normal senior moments. I had been working with

doctors to stay as healthy as I could during the cancer treatment process. He suggested I try Cognify to help with the chemo brain fog.

Less than two weeks after I started taking the Cognify, I began to be able to remember the names of places and people and things. I was just thinking more clearly. I don't think I even realized how bad the brain fog was until it started to lift. But I did wonder if it was just because I was no longer on chemo or if it was because I was taking the Cognify.

Then I went on vacation for some R&R and stopped taking the Cognify. Literally, within one day, I couldn't remember the names of simple objects. Now I knew it really was the Cognify.

Thank you, Cognify, for lifting my brain fog.

14. There are no human clinical studies of CellAssure demonstrating any efficacy in treating cachexia and other cancer-related malnutrition; in improving cancer patients' ability to withstand cancer treatments; or its purported anti-cancer or anti-tumor properties. Likewise, there are no human clinical studies of Cognify demonstrating its efficacy in treating or mitigating chemo brain in cancer patients.

VIOLATIONS OF THE FTC ACT

15. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits “unfair or deceptive acts or practices in or affecting commerce.”

16. Misrepresentations or deceptive omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act.

17. Section 12 of the FTC Act, 15 U.S.C. § 52, prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, CellAssure and Cognify are either “foods” or “drugs” as defined in Section 15(b) and (c) of the FTC Act, 15 U.S.C. § 55(b), (c).

Count I: False or Unsubstantiated Claims

18. Through the means described in Paragraph 13, Defendants have represented, directly or indirectly, expressly or by implication, that:

A. CellAssure

1. treats cachexia and cancer-related malnutrition;
2. improves cancer patients’ ability to withstand cancer treatments, such as surgery, radiation, and chemotherapy; and
3. treats cancer, including cancer tumors; and

B. Cognify treats, mitigates, and prevents cognitive dysfunction caused by cancer treatment (“chemo brain”), including Mild Cognitive Impairment, memory loss, and attentional deficits.

19. The representations set forth in Paragraph 18 are false or misleading, or were not substantiated at the time the representations were made. Therefore, the making of the representations as set forth in Paragraph 18 of this Complaint constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Count II: False Establishment Claims

20. Through the means described in Paragraph 13, Defendants have represented, directly or indirectly, expressly or by implication that:

- A. CellAssure is clinically proven to:
 - 1. treat cachexia and cancer-related malnutrition; and
 - 2. treat cancer, including cancer tumors; and
- B. Cognify is clinically proven to treat, mitigate, and prevent cognitive dysfunction caused by cancer treatment, including Mild Cognitive Impairment, memory loss, and attentional deficits.

21. In truth and in fact,

- C. CellAssure is not clinically proven to:
 - 1. treat cachexia and cancer-related malnutrition; or
 - 2. treat cancer, including cancer tumors; and
- D. Cognify is not clinically proven to treat, mitigate, or prevent cognitive dysfunction caused by cancer treatment, including Mild Cognitive Impairment, memory loss, and attentional deficits.

22. The representations set forth in Paragraph 20 are false or misleading. Therefore, the making of representations set forth in Paragraph 20 of this Complaint constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

CONSUMER INJURY

28. Consumers have suffered and will continue to suffer substantial injury as a result of Defendants' violations of the FTC Act. In addition, Defendants have been unjustly enriched as a result of their unlawful acts or practices. Absent injunctive relief by this Court, Defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

THIS COURT'S POWER TO GRANT RELIEF

29. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of any provision of law enforced by the FTC. The Court, in the exercise of its equitable jurisdiction, may award ancillary relief, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies, to prevent and remedy any violation of any provision of law enforced by the FTC.

PRAYER FOR RELIEF

30. Wherefore, Plaintiff, pursuant to Sections 13(b) of the FTC Act, 15 U.S.C. § 53(b), and the Court's own equitable powers, requests that the Court:

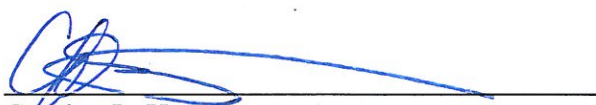
- A. Enter a permanent injunction to prevent future violations of the FTC Act by Defendants;
- B. Award such relief as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of the FTC Act, including but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies; and
- C. Award Plaintiff the costs of bringing this action, as well as such other and additional relief as the Court may determine to be just and proper.

Respectfully submitted,

DAVID C. SHONKA
Acting General Counsel

Dated: _____

1/8/2018



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