

UNITED THERAPEUTICS CORPORATION.

DOCKET NO. C-4089

COMPLAINT

The Federal Trade Commission, having reason to believe that Unither Pharma, Inc., a corporation, and United Therapeutics Corporation, a corporation, have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. a. Respondent Unither Pharma, Inc. (“Unither Pharma”) is a Delaware corporation with its principal office or place of business at 1110 Spring St., Silver Spring, Maryland 20910. Unither Pharma is a wholly owned subsidiary of Unither Pharmaceuticals, Inc., which is wholly owned by respondent United Therapeutics Corporation. Unither Pharma markets and sells an L-arginine-based dietary supplement and a purported medical food under the HeartBar brand name. This dietary supplement purportedly treats or prevents cardiovascular disease and/or improves endurance.

b. Respondent United Therapeutics Corporation (“United Therapeutics”) is a Delaware corporation with its principal office or place of business at 1110 Spring St., Silver Spring, Maryland 20910. United Therapeutics participated in the advertising claims challenged herein, including the creation and dissemination of Exhibits H through J.
2. Respondents have advertised, offered for sale, sold and distributed products to the public, including HeartBar, HeartBar Plus, and HeartBar Sport. These products are “foods” and/or “drugs” within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.
3. The acts and practices of respondents alleged in this complaint have been in or affecting

commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

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website dated March 26, 2002).

F. **How does HeartBar® Work?**

... The active ingredients in HeartBar® have been clinically proven, in properly selected patients, to ... increase pain-free exercise performance.

(Ex. C at 7) (Ex. C consists of webpages from the cookepharma.com website dated March 26, 2002).

G. **How many HeartBars should a consumer eat a day to receive all of the heart and vascular benefits?**

Clinical research shows that, for best results, ... significant improvement (66%) in pain free walking distance ... [is] achieved by eating two bars a day.

(Ex. D at 2) (Ex. D consists of webpages from the cookepharma.com website dated August 20, 2001).

H. HeartBar Sport is a line of L-arginine dietary supplements developed from our experience with HeartBar Plus. HeartBar Sport contains 3 grams of arginine per serving, and it has been shown in clinical trials to improve endurance and energy.

(Ex. C at 3) (Ex. C consists of webpages from the cookepharma.com website dated March 26, 2002).

I. **Who are HeartBar® products for?**

* * * *

HeartBar® Sport, the dietary supplement, is intended for older adults or at-risk individuals who wish to maintain good cardiovascular health, as well as benefit from increased energy and endurance.

(Ex. C at 14-15) (Exhibit F consists of webpages from the cookepharma.com website dated March 26, 2002).

J.

slowly. The great outdoors was getting farther away for LM.

He came to my Vascular Medicine clinic at Stanford in the spring of 1999. I prescribed Trental 400 tid. He returned to me 6 weeks later with little improvement. At that point I stopped the Trental and introduced him to the HeartBar. LM began taking two bars daily. It wasn't long before he noticed an improvement, and over time, he continued to improve. At the time of this writing, LM is able to walk faster, without pain, and considers himself unlimited. He is even able to jog a quarter of a mile before he needs to slow down. He's back to the hills, and enjoying the outdoors again with his son.

I hope that you found these anecdotes interesting. I welcome you to send in your own anecdotes regarding your experience with this nutritional therapy.

With warmest regards,
John P. Cooke, MD Ph.D.
Associate Professor and Director
Section of Vascular Medicine
Stanford University School of Medicine

2. [Doctor's Corner](#)

Alan S. Bailer
Cardiovascular Diseases
1330 Cottman Ave.
Philadelphia, PA 19111

Patient Success Story

My 77 year old father had a triple coronary artery bypass grafting procedure in 1984. ...

* * * *

I am convinced that, without the HeartBars, my father would have had to undergo another revascularization. Thank you, Cooke Pharma, for this wonderful product.

3. [Doctor's Corner](#)

Marcus S. Kryger
Box 280
Forsyth, MO 65653

PVD Patient Success Stories

- 82 Year old white female with ischemic cardiomyopathy and severe peripheral vascular disease by IMEX scan. Unable to walk 1 block due to leg pain and dyspnea. She was scheduled for femoral artery bypass, but started on HeartBar. Three months later, without surgery or other medical changes, she was walking 2 miles daily and continues to do so, without symptoms, 15 months later.
* * * *
 - 86 Year old white male with CHF due to ischemic cardiomyopathy and severe leg pain on walking over 50 feet. Started on HeartBar BID, no other changes in medical regime. A month later he repaired his roof by himself without any symptoms. He felt well for 4 months then stopped HeartBar. He rapidly became more dyspneic; restarted HeartBar BID with prompt improvement and went deer hunting this past fall.
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4. [Doctor's Corner](#)

Peter Gray
90 South St.
Glens Falls, NY 12801

Great Results--Reducing Angina Episodes, Claudication...

Great results regarding:

* * * *

- Reducing claudication.

I'm now using it with my father for claudication with excellent results.

(Ex. C at 8-13) (Ex. C consists of webpages from the cookepharma.com website dated March 26, 2002).

K. The following testimonials from HeartBar customers have appeared on the cookepharma.com website:

1. **Mary R. Gompf** from OH

"It was just like my Doctor said. After only 2 weeks of taking the HeartBar, I noticed a dramatic reduction in my ... leg pain. ...Thank you."

2. **Mr. Barry Dangler** from FL

"...My Cardiologist has taken me off of Imdur for my angina pain now that I'm taking the HeartBar. I feel great."

3. **Ms. Betty Burke** from CA

"I had severe burning pain in my left leg when I ran up hills. My AB Index, done by Stanford Research, in my left leg was only .5. I read on the Internet that a .4 Index might require amputation. After 2 weeks taking the HeartBar, the burning pain is gone! I can run with no pain. I also don't have any leg pain when playing tennis. I was seen by a vascular surgeon who proclaimed that I had excellent circulation in both legs. HeartBar has really changed my life!"

4. **Mr. Sam Roska** from CA

"I have atherosclerosis in both legs. After 2 angioplasties on my legs, my doctor put me on HeartBar. Further angioplasty presented a 20% risk of amputation. I had been able to walk only up to about 3 minutes before debilitating leg pain forced me to stop. After about a month on the HeartBar, I was able to walk 10 minutes with no pain! I

now have much less pain than before.”

5. **Thomas Overbeek** from MI

“I have had leg pains for about 10 years. The pain in my left leg became especially bad in the last 6 months. I could barely walk from the bedroom to the bathroom. I couldn’t stand up without pain. Because of my worsening condition, I was scheduled for bypass surgery in my leg. My doctor told me my pain would remain, however. But, after 2 weeks taking the HeartBar, the pain in my leg disappeared. It was unbelievable! As scheduled, I went into see my surgeon the day before my surgery; he cancelled the surgery. I haven’t felt this good in 10 years. I can walk and climb stairs with no pain now, and can stand for half an hour. ...”

6. **Al White** from MI

“I am almost an Octogenarian (in 6 months)... I have not had to use my Nitro-Stat pills since I started using HeartBars—not a single one. I got my Doctor’s OK first to use the HeartBars.”

(Ex. C at 16-18) (Exhibit F consists of webpages from the cookepharma.com website dated March 26, 2002).

Packaging:

L. Front panel:

HeartBar

Plus

6g L-Arginine per Bar

Clinically Proven Results

* * * *

Reduces angina and leg pain

(Ex. C at 2) (Ex. C consists of webpages from the cookepharma.com website dated March 26, 2002; page 2 depicts packaging for HeartBar Plus).

M. Front panel:

HeartBar

* * * *

Recommended by Doctors for Daily Use

* * * *

• *Helps Reduce... Leg Pain*

* * * *

Back panel:

If you have heart disease, take two HeartBars
a day to feel a difference within two weeks.

Eating two HeartBars a day helps ... with the following results:

- Reduces painful symptoms of heart disease such as ... leg pain

- Helps improve ability to exercise without pain, discomfort ...

(Ex. E at 1-2; citation omitted) (Ex. E is a copy of the packaging for HeartBar).

N. Front Panel:

HeartBar

Sport

Dietary

Supplement

3g L-Arginine per Serving

Clinically Proven Results

Improves endurance... and energy[]

(Ex. F; citation omitted) (Ex. F is a copy of the front of the packaging for HeartBar Sport from 2002).

Other Promotions:

O. **Is HeartBar® Right for You?**

* * * *

If you are elderly, you might want to consider that as we age, our need for arginine in the diet increases. Eaten in the right amount, arginine can help prevent a variety of age-related vascular problems, including “hardening of the arteries” and plaque formation, and prevent or reverse the symptoms associated with them. ...

(Ex. G at 2) (Ex. G is an excerpt from the jewel case insert for *The Heart of the Classics* musical Compact Disc given to HeartBar distributors).

- P. ...[E]ating HeartBar® products ... can improve your aerobic performance. For these reasons, even those who are not experiencing heart disease or age-related symptoms choose to make HeartBar® part of their daily regimen.

Clinical Research Confirms that HeartBar® ...

* * * *

♥ Relieves painful symptoms such as angina and leg pain.

* * * *

(Ex. G at 3) (Ex. G is an excerpt from the jewel case insert for *The Heart of the Classics* musical Compact Disc given to HeartBar distributors).

Q. **See Results in Two Weeks!**

In clinical studies, after only two weeks of eating two HeartBars® daily, patients showed significant improvement in angina scores[¶] In patients suffering from PAD (peripheral artery disease), HeartBar® was shown to significantly improve the ability to walk pain free.[¶] After the initial two weeks, one HeartBar® a day may be sufficient to maintain these results.

* * * *

♥ 70% reduction in angina pain

♥ 66% increase in ability to exercise

(Ex. G at 4; citations omitted) (Ex. G is an excerpt from the jewel case insert for *The Heart of the Classics* musical Compact Disc given to HeartBar distributors).

- R. “In my experience, recommending Heart Bar has helped to stop heart disease in my patients.”

Joe Predergast, M.D.

Diabetes Specialist

(Ex. H. at 2; Ex. K is an excerpt from the 2001 United Therapeutics Corporation Annual Report).

- S. **HeartBar**

... Clinical studies conducted by Cooke Pharma have demonstrated the ability of the HeartBar to reduce painful symptoms associated with cardiovascular diseases Randomized, double-blinded clinical studies published in medical journals and presented at the 2000 American Heart Association meeting have shown that the HeartBar works. ...

(Ex. I. at 2; Ex. I is an excerpt from the 2000 United Therapeutics Corporation Annual Report).

- T. **United Therapeutics Acquiring Cooke Pharma,
Expanding into Angina and Coronary Artery**

5. Through the means described in Paragraph 4, respondents have represented, expressly or by implication, that:

- A. HeartBar substantially decreases leg pain for people with cardiovascular disease;
- B. HeartBar reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, or estrogen deficiency;
- C. HeartBar prevents age-related vascular problems, including “hardening of the arteries” and plaque formation, and reduces the risk of developing cardiovascular disease;
- D. HeartBar reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, and medications, such as nitroglycerin, in patients with cardiovascular disease; and
- E. HeartBar Sport improves endurance and energy for the general population.

6. Through the means described in Paragraph 4, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 5, at the time the representations were made.

7. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 5, at the time the representations were made. Several of the representations are not supported by any clinical studies on humans. Other representations are based on results reported in studies that suffer from various flaws, including the failure to account for the placebo effect and extremely small sample sizes, such that the experience of a single or a few subjects account for the benefits purportedly experienced by the active group as a whole. Therefore, the representation set forth in Paragraph 6 was, and is, false or misleading.

8. Through the means described in Paragraph 4, respondents have represented, expressly or by implication, that clinical studies, research, and/or trials show that:

- A. HeartBar decreases angina pain, including by as much as 70% within two weeks;
- B. HeartBar decreases leg pain while walking or exercising, including by as much as 66%

- C. HeartBar reverses the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart; and
 - D. HeartBar Sport improves endurance and energy for the general population.
9. In truth and in fact, clinical studies, research, and/or trials do not show that:
- A. HeartBar decreases angina pain, including by as much as 70% within two weeks;
 - B. HeartBar decreases leg pain while walking or exercising, including by as much as 66% within two weeks, for people with peripheral artery disease;
 - C. HeartBar reverses the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart; or
 - D. HeartBar Sport improves endurance and energy for the general population.

Therefore, respondents' representations set forth in Paragraph 8, above, were, and are, false or misleading.

10. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission this twenty-second day of July, 2003, has issued this complaint against respondents.

By the Commission.

Donald S. Clark
Secretary

SEAL: