

Complaint

IN THE MATTER OF

UNITHER PHARMA, INC., ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4089; File No. 0223036
Complaint, July 22, 2003--Decision, July 22, 2003

This consent order, among other things, prohibits Respondents Unither Pharma, Inc. and United Therapeutics Corporation – which market HeartBar products, chewy food bars and powders enriched with L-Arginine, vitamins, and minerals – from representing that HeartBar (HeartBar, HeartBar Plus, or HeartBar Sport), or any other L-Arginine product used in or marketed for the treatment, cure, or prevention of cardiovascular disease, or the improvement of cardiovascular or vascular function (1) substantially decreases leg pain for people with cardiovascular disease; (2) reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, estrogen deficiency, or any other medical condition or health risk; (3) prevents age-related vascular problems, including “hardening of the arteries” and plaque formation, or reduces the risk of developing cardiovascular disease; (4) reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, or for medications, such as nitroglycerin, in patients with cardiovascular disease; or (5) improves endurance, circulation, and energy for the general population, unless the claims are substantiated by competent and reliable scientific evidence. The order also requires the respondents to possess competent and reliable scientific evidence to support any future claims about the health benefits, performance, or efficacy of any food, medical food, or dietary supplement used in or marketed for (1) the treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function. In addition, the order prohibits the respondents from misrepresenting, with respect to the above products, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research. The order also requires the respondents notify their distributors as to the claims the Commission has challenged and report to the Commission any distributors who continue to make claims that the Commission’s order prohibits.

Participants

For the Commission: *Matthew Daynard, Keith Fentonmiller, Mary K. Engle and Dennis Murphy.*

For the Respondents: *Daniel Ferrel McInnis, Akin, Gump, Strauss, Hauer & Feld L.L.P.*

Complaint

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.

Complaint

4 Respondents have disseminated or have caused to be disseminated advertisements for HeartBar and HeartBar Plus (collectively “HeartBar”) and HeartBar Sport, including but not necessarily limited to the attached Exhibits A through J. Since at least 1999, advertisements and promotions have appeared on the cookepharma.com and unither.com websites, on product packaging, and/or in print media, such as *Reader’s Digest*, *Modern Maturity*, *Prevention*, *The San Francisco Chronicle*, *The Chicago Sun-Times*, *The Detroit Free Press*, *The Cleveland Plain Dealer*, *The Miami Herald*, and newspaper inserts published by News America Marketing FSI, Inc. HeartBar products are sold in two forms, an edible bar and a powder, which is mixed with water. The bars have sold for approximately \$2 each. According to the product labels, HeartBar and HeartBar Sport contain, among other ingredients, 3 to 6 grams of L-Arginine, soy isoflavones extract, Vitamins A, B-6, B-12, C and E, niacin, folate, iron, and calcium. The advertisements for HeartBar contain the following statements, among others:

Print Advertising:

- A. Today people with heart disease are discovering that taking two HeartBars a day is bringing welcome relief from heart disease symptoms such as ... leg pain - usually within the first two weeks.
One HeartBar a day thereafter may be sufficient to maintain results. ...
Studies show that taking two HeartBars a day ...

* * * *

✓ **Reduce[s] painful symptoms such as angina and leg pain**

* * * *

(Ex. A) (Ex. A is a print advertisement for HeartBar).

B. Here’s what HeartBar can do...

- ✓ Improve ... heart health

* * * *

Complaint

✓ Reduce painful symptoms such as ... leg pain

* * * *

(Ex. B) (Ex. B is a print advertisement for HeartBar).

Internet Advertising:

C. HeartBar® Plus contains 6 grams of arginine per serving, and it has been shown in clinical trials to be effective in ... decreasing angina ... in patients with coronary artery disease. In addition, HeartBar® Plus may be of benefit to selected at-risk population of developing cardiovascular disease.

(Ex. C at 1) (Ex. C consists of webpages from the cookepharma.com website dated March 26, 2002).

D. Eating two **HeartBars** a day ...:

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

* * * *

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

* * * *

Results are usually experienced within the first two weeks. After two weeks, one **HeartBar®** may be sufficient to maintain results.

(Ex. D at 1) (Ex. D consists of webpages from the cookepharma.com website dated August 20, 2001).

E. ...Not to be mistaken for health bar look-alikes, new HeartBar® contains a scientifically proven ingredient to reduce the pain ... associated with vascular disease

* * * *

Fifteen years of scientific research at major institutions reveal that in certain patients the dietary use of the nutritional ingredients in HeartBar®:

- Helps reverse the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart

Complaint

* * * *

(Ex. C at 5-6) (Ex. C consists of webpages from the cookepharma.com 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.

Complaint

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

- J. The following testimonials from doctors have appeared on the cookepharma.com website:

1. **Doctor's Corner**

John P. Cooke
Vascular Medicine
Stanford University School of Medicine
Stanford, CA

A Nutritional Approach to a Healthy Endothelium: Case Histories

I have been studying the endothelium for the better part of two decades, first at Mayo where I was trained, then as an Assistant Professor at Harvard, and now as Associate Professor and Director of the NIH-funded Vascular Medicine Program at Stanford. ...

The HeartBar® has now been tested in rigorous, double-blind, placebo-controlled trials and has been shown to improve exercise tolerance and reduce pain in patients with coronary and peripheral arterial disease. Although these clinical trials are very gratifying, what I find even more satisfying are the positive results that I have observed in my own clinic. Here are a few representative anecdotes:

* * * *

A 78 y/o male with intermittent claudication

L. M. is a vigorous 78 year old man who looks younger than his stated age. As an alpine biologist, one of his classes each year involved a month of hiking over the

Complaint

heights of Yosemite and King's Canyon. Now, in retirement he is still an outdoorsman, and enjoys outdoor activities with his son.

For the last few years though, he had noticed cramping in his legs after walking up a hill. The discomfort would subside if he stood still for a moment, and then he could go on. But about two years ago, the cramping became a real disability for him. He was tightening up after walking a half-mile, and he could only go that far if he walked 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](#)

Complaint

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.

Complaint

* * * *

- 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.
-

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:

Complaint

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

Complaint

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

* * * *

Complaint

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:

Complaint

- 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).

Complaint

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

Complaint

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 Disease**

Silver Spring, MD and Belmont, CA, December 18, 2000 –

* * * *

...Clinical studies conducted by Cooke Pharma have demonstrated convincingly the ability of the HeartBar to reduce painful symptoms of cardiovascular disease.... ...

(Ex. J at 1; Ex. J is a December 18, 2000, press release from the unitedtherapeutics.com website).

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;

Complaint

- 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.

Complaint

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% 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; 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.

Complaint

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

By the Commission.

FREE Help for Heart Disease Sufferers

Get one HeartBar® FREE for EVERY HeartBar You Buy! Or save \$10.00 on a 16-bar carton.

Ask your doctor about taking two HeartBars daily. It can start making a big difference in just two weeks.



For more information about Heartlar or to order directly from us, call toll free (888) 808-6838 or visit our website at www.cookepharma.com. Use under the supervision of a physician. Ask your pharmacist.

Today people with heart disease are discovering that taking two HeartBars a day is bringing welcome relief from heart disease symptoms such as fatigue, chest pain, and leg pain – usually within the first two weeks.

One HeartBar a day thereafter may be sufficient to maintain results.

What people are saying about HeartBar...

"I haven't felt this good in 10 years. I can walk and climb stairs with no pain now... My energy level is also up and I can't wait to get out and do things." – Thomas O., MI

"After taking two HeartBars a day for two weeks, the discomfort in my chest is gone... I'm not afraid to walk alone any more. It's sensational! I'm full of energy." – Mary S., PA

"Several months ago, I was introduced to HeartBars by my cardiologist. I am convinced that this product has greatly improved my quality of life." – Mary Ann D., CA

Visit our web site at www.cookepharma.com
to read what more people are saying.

HeartBar's exclusive formula is based on the science that won the 1998 Nobel prize in medicine. It is the result of ten years of clinical research at America's leading medical institutions. Studies show that taking two HeartBars a day helps open blood vessels and improves circulation to:

- ✓ Help you feel more active and energetic
- ✓ Reduce painful symptoms such as angina and leg pain
- ✓ Improve your tolerance for activity, so you can do more of the things you've always enjoyed

If you have heart disease or a family history of heart disease, ask your doctor about HeartBar, the only medical food for the dietary management of heart and vascular disease. And use the valuable coupons below to try HeartBar and feel the difference for yourself.

Available at these and other fine pharmacies:

CVS/pharmacy ~~Office Drug~~ Simon drugs |  Albertsons
753-7354 plunkett ~~Wichita~~

If your pharmacy has run out of HeartBar and you'd like to take advantage of this free offer, you can purchase HeartBar directly from us: 1) By calling toll-free: 1-888-808-6838 2) By visiting our web site at www.cookepharma.com.

**Recommended by thousands
of cardiologists for relief
of heart disease symptoms.**

MANUFACTURER COUPON	EXPIRATION DATE 06/30/01
---------------------	--------------------------

FREE HeartBar®

Get one HeartBar FREE for EVERY HeartBar you buy!

Use under the supervision of a physician.
Available only at pharmacies.



DISCLAIMER: No coupon given here or purchase of product entitles you to any other coupon listed. There are coupons per purchase. Restrictions may apply. Some items purchased are for flavor of FlavrSaver®. Use of these coupons is prohibited in any country that may apply.

REDEMPTION: Castle Photos, Inc. will reimburse you the face value of the coupon plus the handling & administrative cost. Castle Photos redemption times. Coupons available on request. This coupon is good only when redeemed by you from the company at the time of purchasing product. Coupon may not be doubled or duplicated. Cash value 1/100th cent by Castle Photos, Inc. P.O. Box 4, Belmont, CA 94003



MANUFACTURER COUPON	EXPIRATION DATE 06/30/01
---------------------	--------------------------

SAVE \$10.00

On a 16-bar carton of HeartBar®!

Use under the supervision of a physician.
Available only at pharmacies.



DISCOUNT: This coupon good only on purchase of product indicated. See store for common brand. Limit one coupon per purchase. Restrictions are indicated. Good through purchase of any 16-oz. can of Hunt®. Use if listed, restricted or unlisted by law. Coupons must be used by 12/31/91.

BEHOLDEN Cashio Farms, Inc. will reimburse you the face value of the coupon plus its handling if it is surrendered with Cashio Farms redemption form. Cashes available on request. This coupon is good only when submitted by you from the structure at the time of purchase product. Coupon may not be double or duplicated. Cash value 1/100th of the Cashio Farms, Inc. D.C. Box 4, Phoenix, AZ 85001.



Ex. A

If you have heart disease or are at risk for heart disease...

Free HeartBar® Samples! Call 1-888-808-6838.



Use under the supervision of a physician

If any of these describe you...

- ✓ Diagnosed with heart disease
- ✓ High blood pressure
- ✓ Smoker
- ✓ Estrogen deficiency
- ✓ High cholesterol
- ✓ Weight problem (obesity)
- ✓ Diabetes
- ✓ Family history of heart disease

Here's what HeartBar can do...

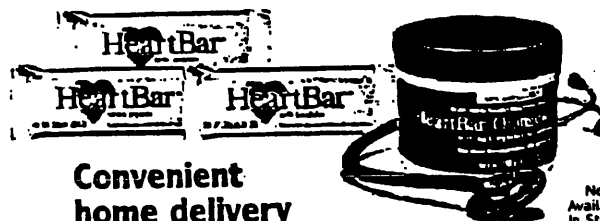
- ✓ Improve circulation and heart health
- ✓ Help you feel more active and energetic
- ✓ Reduce painful symptoms such as angina and leg pain
- ✓ Improve your stamina, so that you can do more of the things you've always enjoyed

Based on Nobel Prize winning science

- Exclusive, patented formula based on the science that won the 1998 Nobel Prize in medicine
- The result of 15 years of clinical research at America's leading medical institutions
- The only medical food for the dietary management of heart and vascular disease
- Recommended by thousands of cardiologists

Delicious new choices

- New low-calorie HeartBar Orange Drink mix (only 40 calories per serving)
- New great tasting HeartBar flavors



Not Available in Stores

Convenient home delivery

- To order, simply call the toll-free number below or visit our web site at www.heartbar.net
- Your order sent via Priority Mail
- This is now the easiest and only way to get HeartBar



**For your free samples,
to order HeartBar, or talk with a
HeartBar Counselor, call toll-free:**

1-888-808-6838

Or visit our web site at www.heartbar.net

Answering America's call for improved heart health

Unither Pharma - HeartBar® Plus, Medical Foods

[Home](#) | [Shop HeartBar](#)

Unither Pharma *Health for a New Generation*

- ◆ [HeartBar® Products](#)
- ◆ [About HeartBar®](#)
- ◆ [Ingredients/Nutrition](#)
- ◆ [Medical Food](#)
- ◆ [Dietary Supplement](#)
- ◆ [Order HeartBar Products](#)
- ◆ [Company Information](#)
- ◆ [About Unither Pharma](#)
- ◆ [Scientific Advisory Board](#)
- ◆ [Contact](#)
- ◆ [Science Library](#)
- ◆ [Definition of Terms](#)
- ◆ [Reviews](#)
- ◆ [Journal Abstracts](#)
- ◆ [Clinical Studies](#)
- ◆ [Pre-Clinical Studies](#)
- ◆ [About Heart Disease](#)
- ◆ [Doctor's Corner](#)
- ◆ [Frequently Asked Questions](#)
- ◆ [Testimonials](#)
- ◆ [MD Mentors Locator](#)
- ◆ [Customer's Corner](#)
- ◆ [Frequently Asked Questions](#)
- ◆ [Testimonials](#)
- ◆ [A United Therapeutics Corporation Company](#)

HeartBar® Plus - Medical Food



The HeartBar® Plus Product Line - Six Delicious Flavored Bars and an Orange-Flavored Powdered-Drink.

HeartBar® Plus is a line of L-arginine-based medical foods, clinically proven to be safe and effective in the dietary management of people with or at risk of developing cardiovascular disease. It is the first medical food to be listed in the Physician's Desk Reference.

HeartBar® Plus contains 6 grams of arginine per serving, and it has been shown in clinical trials to be effective in enhancing the exercise capacity while decreasing angina while improving the quality of life in patients with coronary artery disease. In addition, HeartBar® Plus may be of benefit to selected at-risk population of developing cardiovascular disease.

Normal dietary sources of L-arginine include nuts, red meat, and seafood; they are usually high in fat content, not desirable for daily consumption by patients with heart disease.

HeartBar® Plus is a convenient dietary source of L-arginine, suitable for daily consumption. For example, a single serving of HeartBar® Plus contains 6 g of L-arginine, which is equivalent to consuming three steaks, or two lobsters, or twelve 500 mg

Unither Pharma - HeartBar® Plus, Medical Foods

Page 2 of 2

arginine plus.

Cardiovascular disease is a serious condition. Patients should not undertake any type of self-diagnoses or self-treatment without the active supervision of a physician. Heartbar® Plus is a medical food, not a conventional food, and is intended for use by patients who are under the care of a physician.



If you have any questions, please feel free to contact us.

All Rights Reserved, Unither Pharma 2001, 2002

44 x 6.5 A 2

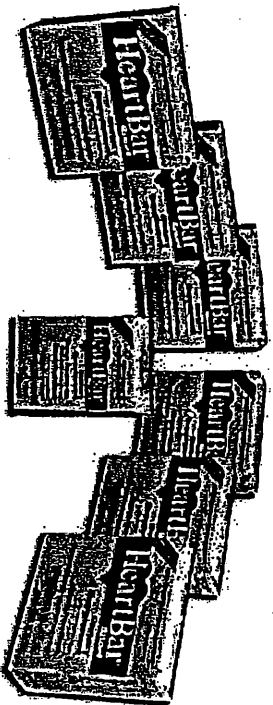
Unither Pharma

Health for a New Generation

- ◆ HeartBar® Products
- ◆ About HeartBar®
- ◆ Ingredients/Nutrition
- ◆ Medical Food
- ◆ Dietary Supplement
- ◆ Order HeartBar Products
- ◆ Company Information
- ◆ About Unither Pharma
- ◆ Scientific Advisory Board
- ◆ Contact
- ◆ Science Library
- ◆ Definition of Terms
- ◆ Reviews
- ◆ Journal Abstracts
- ◆ Clinical Studies
- ◆ Pre-Clinical Studies
- ◆ About Heart Disease
- ◆ Doctor's Corner
- ◆ Frequently Asked Questions
- ◆ Testimonials
- ◆ MD Mentors Locator
- ◆ Customer's Corner
- ◆ Frequently Asked Questions
- ◆ Testimonials
- ◆ A United Therapeutics Corporation Company

Home | Shop HeartBar

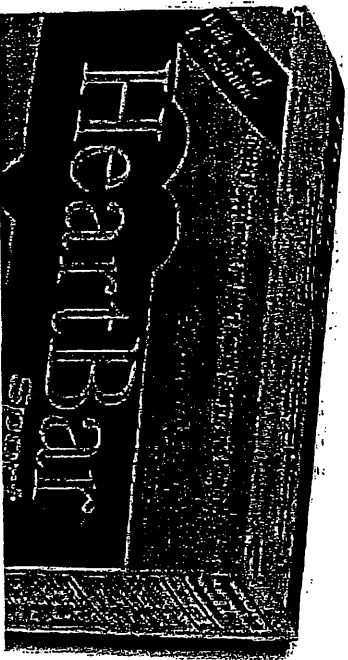
HeartBar® Sport - Dietary Supplement



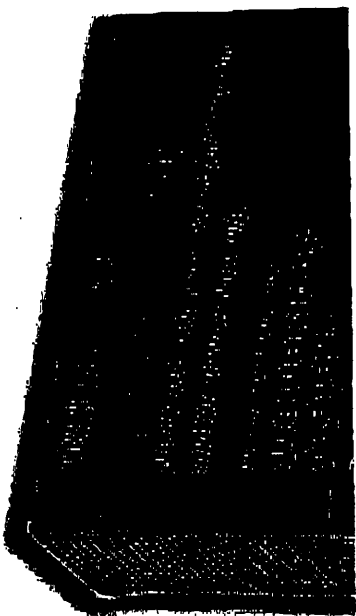
The HeartBar Sport® Product Line - Six Delicious Flavored Bars and an Orange-Flavored Powdered-Drink.

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.

Millions of Americans are looking for ways to remain fit and healthy for their entire lifetime, and age should not be a barrier to living a full and productive life. Adding HeartBar Sport to your diet may help you lead a more active lifestyle.



Unither Pharma - Heartbar® Sport, Dietary Supplements



If you have any questions, please feel free to contact us.

All Rights Reserved, Unither Pharma 2001, 2002

• hot dogs, fatty red meats • butter, egg yolks, and cheese • organ meats like liver, sweetbreads, kidney, and brain • whole milk, cream, and ice cream	• margarine, and lard • baked goods made with egg yolks and saturated fats • saturated oils like coconut, palm, and palm kernel oil • fried foods
--	--

Certain vitamins have been shown to be beneficial when included in a healthy diet. Antioxidants which are found in vegetables and fruit may reduce the chance of having a heart attack. They work by preventing the damaging effects of free radicals, which can damage cells and cause cholesterol buildup. Niacin, when taken in high doses, lowers triglycerides (fat) and cholesterol as it raises the levels of high-density lipoprotein (HDL). HDL attach themselves to excess cholesterol in the lining of the blood vessels and pass it out of the body. Finally, there's folic acid. This lowers homocysteine (an amino acid) levels in the blood, which may be a factor in clogging arteries. Folic acid should be taken along with vitamin B12.

Heart Bar™ raises the bar on the dietary management of cardiovascular disease

HeartBar® is the first medical food intended for the dietary management of cardiovascular disease. The US Food and Drug Administration (FDA) has defined a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." [21 U.S.C. § 360ee(b)(3)]. It is intended for use under the supervision of a physician.

While this new category of dietary management of cardiovascular disease is very exciting to the medical community, the specifics about new HeartBar® are even more so. Not to be mistaken for health bar look-alikes, new HeartBar® contains a scientifically

proven ingredient to reduce the pain and fatigue associated with vascular disease, helping patients feel better and become more active after only 2 weeks. How can new HeartBar® do all that? Here's how:

HeartBar® contains a patented formulation designed to increase the body's production of nitric oxide. Research has shown that many patients with heart disease have deficient levels of nitric oxide. The body uses nitric oxide to dilate or widen the blood vessels and allow blood to flow more freely. Nitric oxide also helps prevent cholesterol and platelets from sticking to the blood vessels' walls, which would further inhibit free blood flow.

Fifteen years of scientific research at major institutions reveal that in certain patients the dietary use of the nutritional ingredients in HeartBar®:

- Helps reverse the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart
- Promotes better circulation for better heart health
- Restores blood vessel function for those at risk for or with heart disease

Daily use of this chewy, delicious HeartBar® may be able to help you take a bite out of the painful and life-limiting symptoms of cardiovascular disease. Patients may also benefit from its many other nutrients, which include antioxidants like [such as] vitamins C, E, B6, and B12, as well as potassium, folic acid, niacin, and fiber.

Ask your doctor whether adding HeartBar® to your diet can raise the bar for your cardiovascular health.

If you have any questions or want more information about cardiovascular health, talk with your doctor or health care professional. This general information on cardiovascular disease presented was adapted from information presented by the American Heart Association (AHA) and American Dietetic Association (ADA).

ENC 0.4

their arginine from red meats, which is not a desirable source of L-arginine.

[\[back to top\]](#)

How does HeartBar® Work?

HeartBar® is based on a unique biological marker (indicator). Rather than using high cholesterol as a biological marker of the development of atherosclerosis, Unither has developed a new approach measuring the endothelial production of nitric oxide. Endothelial nitric oxide production is often reduced in people with cardiovascular and peripheral arterial disease as well as those with risk factors for these diseases. The active ingredients in HeartBar® have been clinically proven, in properly selected patients, to restore nitric oxide production, improve vascular function and increase pain-free exercise performance. HeartBar® Plus, the medical food, is intended for use under the supervision of a physician.

[\[back to top\]](#)

Why can't patients just take an L-arginine pill?

Heart disease patients and healthy individuals CAN take arginine supplement pills, but taking arginine pills are not as convenient as taking a single serving of the deliciously-flavored HeartBar® product. For example, arginine pills usually contain 500 to 750 mg of L-arginine, and a single serving of HeartBar® Plus contains as much L-arginine as twelve 500 mg arginine pills (see table below.) As you can see, HeartBar® products are a more convenient supplemental dietary source of L-arginine.

Uniher Pharma

Health for a New Generation

HeartBar® Products

◆ About HeartBar®

◆ Ingredients/Nutrition

◆ Medical Food

◆ Dietary Supplement

◆ Order HeartBar® Products

◆ Company Information

◆ About Uniher Pharma

◆ Scientific Advisory Board

◆ Contact

◆ Science Library

◆ Definition of Terms

◆ Reviews

◆ Journal Abstracts

◆ Clinical Studies

◆ Pre-Clinical Studies

◆ About Heart Disease

◆ Doctor's Corner

◆ Frequently Asked Questions

◆ Testimonials

◆ MD Mentors Locator

◆ Customer's Corner

◆ Frequently Asked Questions

◆ Testimonials

◆ A United Therapeutics Corporation Company

Home | Shop HeartBar

Doctor's Corner

John P. Cooke
Vascular Medicine
Stanford University School of Medicine
Stanford, CA

A Nutritional Approach to a Healthy Endothelium: Case Histories

I have been studying the endothelium for the better part of two decades, first at Mayo where I was trained, then as an Assistant Professor at Harvard, and now as Associate Professor and Director of the NIH-funded Vascular Medicine Program at Stanford. The endothelial lining of blood vessels is only one cell layer thick, but it exerts tremendous control over vessel tone, by producing Nitric Oxide(NO), prostacyclin, and other vasodilators. An endothelial enzyme known as NO synthase, produces NO and citrulline from the amino acid L-arginine. In patients with atherosclerosis, or with risk factors for atherosclerosis, the production of NO is reduced. Vasodilation is impaired in these individuals, and this impairment of endothelial function contributes to reduced coronary and peripheral blood flow. My group was the first to show that the impairment of NO synthesis could be reversed simply by administering exogenous L-arginine. Since then a number of groups including our own, have shown that high doses of arginine(6-9 grams daily) can improve coronary and peripheral blood flow, improve exercise tolerance and relieve symptoms of angina and intermittent claudication. However, it is difficult for patients to take 12-18 capsules of L-arginine daily, which is why I developed the arginine-enriched HeartBar®

The HeartBar® has now been tested in rigorous, double-blind, placebo-controlled trials and has been shown to improve exercise tolerance and reduce pain in patients with coronary and peripheral arterial disease. Although these clinical trials are very gratifying, what I find even more satisfying are the positive results that I have observed in my own clinic. Here are a few representative anecdotes:

A 65 y/o male with chest pain

Mr. M. is the chief executive officer of an educational company. His job is stressful, and his hypertension, hypercholesterolemia, and diabetes have, over the years, taken a toll on his heart. In 1975 he underwent coronary artery bypass grafting X3 (at that time he stopped smoking). Since then he has had two myocardial infarctions and multiple angioplasties. He presented to my clinic in 1995, with an exacerbation of his angina. I increased his medical therapy, getting his blood pressure, diabetes and high cholesterol under control. However, despite the best medical therapy he showed up in my clinic again in 1998 with more chest pain. Coronary angiography at that time showed that his bypass grafts were diffusely diseased, and the severity of disease in his native vessels would make revascularization difficult. He was already on maximal medical therapy, and he was taking nitroglycerin about 3-6 times daily for breakthrough chest pain. I told Mr. M. that he would need to make some lifestyle changes (exercise, stress reduction, diet) to enhance his heart (and endothelial) health. I also asked him to try the HeartBar.

At his next visit to me a couple of weeks later, Mr. M. was radiant. The angina had improved markedly. He rarely needed to use nitroglycerin. He was even able to get back to his old work schedule. At the time of this writing, Mr. M. is enjoying life with less pain.

A 78 y/o male with intermittent claudication

L. M. is a vigorous 78 year old man who looks younger than his stated age. As an alpine biologist, one of his classes each year involved a month of hiking over the heights of Yosemite and King's Canyon. Now, in retirement he is still an outdoorsman, and enjoys outdoor activities with his son. For the last few years though, he had noticed cramping in his legs after walking up a hill. The discomfort would subside if he stood still for a moment, and then he could go on. But about two years ago, the cramping became a real disability for him. He was tightening up after walking a half-mile, and he could only go that far if he walked 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

If you have any questions, please feel free to contact us.

All Rights Reserved, Unither Pharma 2001, 2002

Unither Pharma - Doctor's Corner

[Home](#) | [Shop HeartBar](#)

Unither Pharma *Health for a New Generation*

- ◆ HeartBar® Products
- ◆ About HeartBar®
- ◆ Ingredients/Nutritious
- ◆ Medical Food
- ◆ Dietary Supplement
- ◆ Order HeartBar Products
- ◆ Company Information
- ◆ About Unither Pharma
- ◆ Scientific Advisory Board
- ◆ Contact
- ◆ Science Library
- ◆ Definition of Terms
- ◆ Reviews
- ◆ Journal Abstracts
- ◆ Clinical Studies
- ◆ Pre-Clinical Studies
- ◆ About Heart Disease
- ◆ Doctor's Corner
- ◆ Frequently Asked Questions
- ◆ Testimonials
- ◆ MD Mentors Locator
- ◆ Customer's Corner
- ◆ Frequently Asked Questions
- ◆ Testimonials

A United Therapeutics Corporation Company

Doctor's Corner

Alan S. Bailor
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. He was angina free for approximately 10 years. Gradually, since that time, he has experienced progressive angina with exertion. His medications include Norvasc, Imdur, Atenolol, and sublingual Nitroglycerin.

Understandably, he is not anxious to undergo repeat revascularization. Approximately 18 months ago, I read studies which confirmed that L-Arginine, in the form of the HeartBar, increased the blood flow through the coronary arteries substantially. I suggested that my father try one HeartBar twice daily. After approximately 6 weeks of adding two HeartBars daily to his regimen, he is rarely experiencing angina and has none at rest presently.

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

If you have any questions, please feel free to [contact us](#).

All Rights Reserved, Unither Pharma 2001, 2002

Ex 1

Unither Pharma

Health for a New Generation

[Home](#) | [Shop HeartBar](#)

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.
- 50 Year old male with persistent polymorphic ventricular ectopy and paroxysmal dyspnea, 4 months after PTCA/stent placement (with good angiographic results). Two weeks after starting HeartBar, all symptoms resolved, and remains asymptomatic and fully functional 18 months later on 1 HeartBar daily.
- 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.

If you have any questions, please feel free to [contact us](#).

All Rights Reserved, Unither Pharma 2001, 2002

- HeartBar® Products
 - ◆ [About HeartBar®](#)
 - ◆ [Ingredients/Nutrition](#)
 - ◆ [Medical Food](#)
 - ◆ [Dietary Supplement](#)
 - ◆ [Order HeartBar Products](#)
- Company Information
 - ◆ [About Unither Pharma](#)
 - ◆ [Scientific Advisory Board](#)
 - ◆ [Contact](#)

- Science Library
 - ◆ [Definition of Terms](#)
 - ◆ [Reviews](#)
 - ◆ [Journal Abstracts](#)
 - ◆ [Clinical Studies](#)
 - ◆ [Pre-Clinical Studies](#)
 - ◆ [About Heart Disease](#)
- Doctor's Corner
 - ◆ [Frequently Asked Questions](#)
 - ◆ [Testimonials](#)
 - ◆ [MD Mentors Locator](#)
- Customer's Corner
 - ◆ [Frequently Asked Questions](#)
 - ◆ [Testimonials](#)
- [A United Therapeutics Corporation Company](#)

Unither Pharma

Health for a New Generation

[Home](#) | [Shop HeartBar](#)

HeartBar® Products

- ◆ [About HeartBar®](#)
- ◆ [Ingredients/Nutrition](#)
- ◆ [Medical Food](#)
- ◆ [Dietary Supplement](#)
- ◆ [Order HeartBar Products](#)
- ◆ [Company Information](#)
- ◆ [About Unither Pharma](#)
- ◆ [Scientific Advisory Board](#)
- ◆ [Contact](#)

Science Library

- ◆ [Definition of Terms](#)
- ◆ [Reviews](#)
- ◆ [Journal Abstracts](#)
- ◆ [Clinical Studies](#)
- ◆ [Pre-Clinical Studies](#)
- ◆ [About Heart Disease](#)

Doctor's Corner

- ◆ [Frequently Asked Questions](#)
- ◆ [Testimonials](#)
- ◆ [MD Mentors Locator](#)
- ◆ [Customer's Corner](#)
- ◆ [Frequently Asked Questions](#)
- ◆ [Testimonials](#)

[A United Therapeutics Corporation Company](#)

Doctor's Corner

Peter Gray
90 South St.
Glens Falls, NY 12801

Great Results--Reducing Angina Episodes, Claudication, Improving Exercise Capacity

Great results regarding:

- Improving exercise capacity in patients with stable angina,
- Reducing anginal episodes, and
- Reducing claudication.

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

If you have any questions, please feel free to [contact us](#).

All Rights Reserved, Unither Pharma 2001, 2002

EX-13
12

Unither Pharma

Health for a New Generation

[Home](#) | [Shop HeartBar](#)

Frequently Asked Questions for Patients

Don't see an answer to your question, please [contact us](#).

Table of Contents

- ◆ [HeartBar® Products](#)
 - ◆ [About HeartBar®](#)
 - ◆ [Ingredients/Nutritious](#)
 - ◆ [Medical Food](#)
 - ◆ [Dietary Supplement](#)
 - ◆ [Order HeartBar Products](#)
 - ◆ [Company Information](#)
 - ◆ [About Unither Pharma](#)
 - ◆ [Scientific Advisory Board](#)
 - ◆ [Contact](#)
 - ◆ [Science Library](#)
 - ◆ [Definition of Terms](#)
 - ◆ [Reviews](#)
 - ◆ [Journal Abstracts](#)
 - ◆ [Clinical Studies](#)
 - ◆ [Pre-Clinical Studies](#)
 - ◆ [About Heart Disease](#)
 - ◆ [Doctor's Corner](#)
 - ◆ [Frequently Asked Questions](#)
 - ◆ [Testimonials](#)
 - ◆ [MD Mentors Locator](#)
 - ◆ [Customer's Corner](#)
 - ◆ [Frequently Asked Questions](#)
 - ◆ [Testimonials](#)
 - ◆ [A United Therapeutics Corporation Company](#)
-
- [What is HeartBar®?](#)
 - [Who are HeartBar® products for?](#)
 - [What's in HeartBar®?](#)
 - [What is L-arginine?](#)
 - [How does HeartBar® Work?](#)
 - [Is HeartBar® Plus a replacement for existing medical approaches to treating coronary artery and vascular disease?](#)
 - [What are the contraindications for HeartBar®?](#)
 - [What foods do you have to eat to get a lot of L-arginine?](#)
 - [What is the scientific justification for the product?](#)
 - [Are there any adverse effects from eating HeartBar®?](#)
 - [Who regulates medical foods?](#)
 - [What are other examples of medical foods?](#)
-

What is HeartBar®?

See [What is HeartBar®?](#)

[\[back to top\]](#)

Who are HeartBar® products for?

HeartBar® products are designed for different individuals:

414
JUL
2014

HeartBar® Plus, the medical food, is intended for cardiovascular patients who are under the active care of a physician. It is a safe, effective and convenient way that may significantly increase nitric oxide production for an estimated 16 million people who have been diagnosed with coronary and peripheral artery disease. Extensive scientific research shows that nitric oxide is deficient in people with these diseases as well as those with risk factors for heart disease such as high cholesterol, high blood pressure, diabetes, estrogen deficiency and tobacco use.

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.

[\[back to top\]](#)

What's in HeartBar®?

See [Nutritional Content](#).

[\[back to top\]](#)

What is L-arginine?

See [L-arginine](#).

[\[back to top\]](#)

How does HeartBar® Work?

The active ingredient of all HeartBar® products is L-arginine, an amino acid used by the human body to

Unither Pharma - Customer's Testimonials

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 angina pain and leg pain. My energy level also increased, allowing me to do more things with my great-grand children that I previously lacked the energy to do. Thank you."

Ms. Jean Lariscy from GA

"I have had so many tests done by the hospital for the burning and pain in my feet and legs. I have taken so many different kinds of medication and nothing has helped. My Cardiologist found I had mild atherosclerosis and believed the HeartBar would help. Within 2 weeks I noticed an improvement. My circulation has improved, my energy has increased, and the burning in my legs and feet and hip is so much better. Thanks to HeartBars. I have told my friends about the HeartBar and suggested they talk to their cardiologist."

Ms. Jerree Perry from KY

"I have lots of 'Natural Energy'. Instead of 52 years of age. I feel 32. I walk 3 to 5 miles a day after working 8 to 10 hours. It can be a 'Life Change'. Thanks."

Bernadette Reid from NY

"I don't expect a cure, but it is just so good not to have that leg pain any more. I can walk so much further."

Mr. Barry Dangler from FL

"My Cardiologist recommended the HeartBar to me. After about 2 weeks, people at work were asking me, 'Barry, what's going on?' I told them about the HeartBar and how much more energy I now have. I was very tired and sleeping a lot. Now I'm back doing things, like yard work, that I haven't done in 2 years. My Cardiologist has taken me off of Indur for my angina pain now that I'm taking the HeartBar. I feel great."

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."

EX-CA 16
F.D. 12

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!

William E. Doxon from KS

"My name is William E. Doxon. I would like to give you a short overview of my heart and subsequent diabetes history and my experience with HeartBar. I had open-heart surgery in November of 1976. Since then I have had 3 ballooning. I had a light heart attack during the last ballooning. The doctors told me I probably would have a major attack at some point. One month later I did. After taking various heart medications for years, I developed diabetes. My legs and feet have been icy cold for some time. My hips and legs hurt whether working or at rest. In my work, I unload freight loads of chemicals used in commercial dishwashers. I also service the machines.

In July of 1999 my doctor couldn't find a pulse in either foot. I went to a vascular specialist who put in 2 stents, one in each groin area. Still no pulse! In December of 1999 I went back to the same specialist who then put three more stents in the same area. Still no pulse in my feet!

About two weeks after the last stents, my doctor called and asked me to try a new product called HeartBar. I was to eat two a day. I used them as my midmorning and midafternoon snacks. Within two weeks, I had a weak pulse in both feet. Since then, the pulse has gotten stronger. In fact, I've had to take my shoes off sometimes because my feet were so warm. I can now work or walk without pain. I firmly believe that anyone with vascular problems will benefit from eating two HeartBars a day. I get tired of having to remember to eat anything twice a day. But this is, after all, a medication and should be treated as such. Thanks Cooke Pharmalll."

Ms. Dorothy Johnston from CA

"Before taking the HeartBar, I had to stop half way up the 15 stairs to my house. I also had to stop part way up an incline to the building where I did my pool therapy because of my angina pain. Now I can walk the stairs and to the pool without stopping and with no pain. I'm also walking 20 minutes to half an hour with a friend at least once a week with no problem. HeartBar has

EX-17
F.D. 17

Unitier Pharma - Customer's Testimonials

"really made a big difference in my daily life."

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."

Charles Schiele from CA

"At a friend's recommendation, I started on the HeartBar about 6 weeks ago. My energy level has really increased. I've more tripled the number of laps I swim to 20 now, and can swim these faster than before, even the last lap. When I'm done, I feel great; my stamina has so greatly improved. Additionally, my blood pressure has dropped and my appetite for healthy foods has increased. I've also started lifting weights with all this new energy. I feel like a kid again."

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. My energy level is also up and I can't wait to get out to do things. HeartBar has given me back my life!"

Al White from MI

"I am almost an Octogenarian (in 6 months). My angina pains have left me and my breathing has become a lot easier. I have not had to use my Nitro-Stat pills since I started using the HeartBars—not a single one. I got my Doctor's OK first to use the HeartBars."

Mary Sutton from PA

Ex.C p.18
Ex.F p.18

HeartBar®
[Home](#) | [Peer Counselor Login](#) | [Peer-to-Peer Marketing](#) | [Peer Counselor Application](#)
[Request HeartBar® Samples](#) | [Order HeartBar® Products](#) | [Find a Peer Counselor](#)
Product Information

- ◆ About HeartBar®
- ◆ Product Line
- ◆ Patients FAQs
- ◆ Doctors FAQs
- ◆ Common Terms

Company Information

- ◆ Contact Information
- ◆ News
- ◆ Background

Science Library

- ◆ Reviews
- ◆ Medical Abstracts
- ◆ Clinical Studies
- ◆ Pre-Clinical Studies
- ◆ About Heart Disease

Scientific Advisory**Patients' Testimonials****Doctor's Corner**

A Unither Pharmaceuticals
Company

About HeartBars

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

Recommended by doctors for daily use
Based on Nobel Prize medical science and clinical research

Eating two **HeartBars** a day helps open blood vessels and improves
circulation with the following results:

- Reduces painful symptoms of heart disease such as angina and leg pain
- Helps increase mobility
- Helps improve ability to exercise without pain, discomfort, or fatigue
- Increases energy levels to help you live a more active and enjoyable life

Results are usually experienced within the first two weeks. After two weeks, one **HeartBar®** a day may be sufficient to maintain results.

HeartBar® was developed following ten years of extensive research at Stanford University and other leading medical centers.

Based on the science that won the 1998 Nobel Prize in medicine, **HeartBars** feature a patented formula containing L-arginine, which helps improve circulation and create smoother, more efficient blood flow.

Ask your doctor or medical professional about **HeartBars**, and learn how it helps people with heart disease to live a more active and enjoyable life.

If you have any questions, please feel free to contact us.

All Rights Reserved, Cooke Pharma 2001

The price for 32 servings any combination of HeartBar® products is as follows:

- \$59.99 for a single 32-serving order, plus shipping & handling
- \$49.99 for a 32-serving subscription order, plus shipping & handling

[\[back to top\]](#)

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 in blood circulation, significant improvement (66%) in pain free walking distance and reduction in total and LDL cholesterol by 10%-15%, are achieved by eating two bars a day.

Check out the HeartBar® product line for the new and exciting flavors!

[\[back to top\]](#)

Who regulates medical foods?

The U.S. Food and Drug Administration regulates medical foods. By law, medical foods are products specially formulated to supplement oral intake as part of the diet in the overall medical management of a condition or disease for which distinct nutritional requirements are established by medical evaluation. Medical foods are only for use under the supervision of a physician. HeartBar® meets the requirements of a medical food.

[\[back to top\]](#)

What are other examples of medical foods?

HeartBar® meets the requirements of a medical food product. According to the FDA, other examples of medical foods include products for kidney and liver disease, compromised immune functions, diabetes, burns, Crohn's Disease and short bowel syndrome. They are not intended for use like conventional food.

[\[back to top\]](#)

When was Cooke Pharma established?

The Only Medical Food for the Dietary Management of Vascular Disease

HeartBar®

Use under the supervision of a physician.

Ask your pharmacist.

Recommended by Doctors for Daily Use

- *Improves Circulation*
- *Helps Reduce Angina & Leg Pain*
- *Provides Increased Energy*

16 50g (1.76 OZ) HeartBars
NET WT. 800g (28.2 OZ [1 LB 12.2 OZ])

Ex. H. p. 1

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

Eating two HeartBars a day helps open blood vessels
and improves circulation with the following results:

- Reduces painful symptoms of heart disease
such as angina and leg pain
 - Helps increase mobility
- Helps improve ability to exercise without pain,
discomfort, or fatigue
- Increases energy levels to help you live a
more active and enjoyable life

Results are usually experienced within the first two weeks.
After two weeks, one HeartBar® a day may be sufficient to maintain results.

Use under the supervision of a physician. Ask your pharmacist.



Distributed by Cooke Pharma Inc., Belmont CA 94002
For more information about HeartBar®,
call us toll free at (888) 808-6838
or visit our web site at www.cookepharma.com

1700L 32oz

Dietary Supplement for Heart Health, Energy, and Vitality

Cranberry
Flavored

HeartBar®

Sport

Dietary Supplement

3g L-Arginine per Serving

Clinically Proven Results

*Improves endurance, circulation and energy**

*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.

8 BARS | NET WT 9.87 OZ (280g)

The Heart of the Classics

The Finest Classical Music...A Gift to You From HeartBar®

HeartBar
HeartBar
HeartBar

Is HeartBar® Right For You?

Anyone concerned about the health of their heart will appreciate the benefits of adding HeartBar to his or her diet. Because HeartBar is high in protein, vitamins, and minerals, and also low in fat and calories, it is an ideal snack food or meal replacement for those who are on the go or are watching their weight.

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. If you have any of the following risk factors or symptoms of heart disease, HeartBar may be an important part of your daily health program:

Risk Factors

- ♥ High Cholesterol
- ♥ High Blood Pressure
- ♥ Obesity
- ♥ Diabetes
- ♥ Low Estrogen
- ♥ Smoker
- ♥ Family History

Symptoms

- ♥ Chest pains
- ♥ Leg Pains
- ♥ Winded When Climbing Stairs
- ♥ Low Energy



is the smart choice

Call HeartBar® Toll Free 1 888 808 6838

HeartBar® Improves Your Blood Flow.

Because the key ingredient in HeartBar® improves the elasticity of your blood vessels and helps to keep vessels open, eating HeartBar® products can contribute to better blood flow throughout your body and can improve your aerobic performance. For these reasons, even those who are not experiencing heart disease or age-related symptoms choose to make HeartBar® a part of their daily regimen.

Clinical Research Confirms that HeartBar®...

- ♥ Improves circulation and blood flow for better heart health.
- ♥ Increases exercise ability and improves energy levels.
- ♥ Relieves painful symptoms such as angina and leg pain.
- ♥ Has been proven safe and effective.

If you are...

- ♥ Athletic
- ♥ Under Stress
- ♥ Dieting
- ♥ Elderly

**YOU WOULD NEED TO TAKE UP TO 12 LARGE,
ARGININE PILLS PER DAY TO EQUAL THE
AMOUNT OF ARGININE IN JUST 2 HEARTBARS®.**



is the smart choice

Call HeartBar® Toll Free 1 888 808 6838

See Results in Two Weeks!

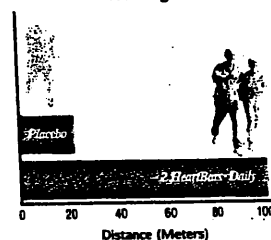
In clinical studies, after only two weeks of eating two HeartBars® daily, patients showed significant improvement in angina scores and quality of life.¹ In patients suffering from PAD (peripheral artery disease), HeartBar® was shown to significantly improve the ability to walk pain free.² After the initial two weeks, one HeartBar® a day may be sufficient to maintain these results.

- ♥ 150% improvement in coronary blood flow response
- ♥ 70% reduction in angina pain
- ♥ 66% increase in ability to exercise

**For More Information,
Or To Order HeartBar®,
Call Us Today!**

*Free Sample Kit Available.
Ask Us About Our Special Discount Program.*

Change in Pain-Free
Walking Distance



1. Maxwell AJ, Zapein MP, Cooke JP. Endothelial dysfunction in hypercholesterolemia is reversed by a nutritional product designed to enhance nitric oxide activity. *Circulation Drug Ther.* 2000;6(1):58.
2. Data available. Cooke Pharma, Inc.

Try HeartBar® Today... It really works!

"I couldn't even walk a hole on the golf course without a golf cart. And, I couldn't walk over a quarter mile without pain in my legs. Now I have no pain." — Gary Martinelli, California

Call HeartBar® Toll Free 1 888 808 6838



2001 United Therapeutics Corporation Annual Report

**Medicines
for Life[®]**

Arginine Is Patented for the Treatment of Cardiovascular Disease

Amino acids have been known for many years. However, until recent years, their place in the amino acid family was not fully appreciated. Arginine is a natural amino acid that has been found to be essential for the treatment of cardiovascular disease. The discovery of this therapeutic amino acid was made by Dr. John Cook, M.D., Ph.D., Professor of Medicine at Stanford University. Dr. Cook's research has led to the discovery of the amino acid arginine, which is now being used in the treatment of cardiovascular disease. Dr. Cook's research is being used to develop new treatments for cardiovascular disease.



"In my experience, recommending Heart Bar has helped to stop heart disease in my patients."

Joe Prendergast, M.D.
Diabetes Specialist

Arginine is a natural amino acid that has been found to be essential for the treatment of cardiovascular disease. The discovery of this therapeutic amino acid was made by Dr. John Cook, M.D., Ph.D., Professor of Medicine at Stanford University. Dr. Cook's research has led to the discovery of the amino acid arginine, which is now being used in the treatment of cardiovascular disease. Dr. Cook's research is being used to develop new treatments for cardiovascular disease.

In earlier centuries, when average life expectancy was around 40 years, the risk of cardiovascular disease was not the biggest concern. In those days, infectious diseases took most people's lives. However, in the 20th century, as life expectancy increased, the risk of cardiovascular disease became a major concern. In the United States and Europe, heart disease is the leading cause of death. Arginine supplementation has been found to be effective in the treatment of cardiovascular disease. It has been found that arginine supplementation can help to lower blood pressure, improve blood flow, and reduce the risk of heart disease.

Arginine is a natural amino acid that has been found to be essential for the treatment of cardiovascular disease. The discovery of this therapeutic amino acid was made by Dr. John Cook, M.D., Ph.D., Professor of Medicine at Stanford University. Dr. Cook's research has led to the discovery of the amino acid arginine, which is now being used in the treatment of cardiovascular disease. Dr. Cook's research is being used to develop new treatments for cardiovascular disease.

Recent studies show that people with high levels of cholesterol, called "bad cholesterol," are at a higher risk of heart disease. Arginine supplementation has been found to be effective in the treatment of heart disease. It has been found that arginine supplementation can help to lower cholesterol levels, improve blood flow, and reduce the risk of heart disease.

Arginine is a natural amino acid that has been found to be essential for the treatment of cardiovascular disease. The discovery of this therapeutic amino acid was made by Dr. John Cook, M.D., Ph.D., Professor of Medicine at Stanford University. Dr. Cook's research has led to the discovery of the amino acid arginine, which is now being used in the treatment of cardiovascular disease. Dr. Cook's research is being used to develop new treatments for cardiovascular disease.

In the development of Heart Bar, Dr. Cook's research was used to develop a new treatment for cardiovascular disease. Heart Bar is a natural amino acid supplement that has been found to be effective in the treatment of cardiovascular disease. It has been found that Heart Bar can help to lower blood pressure, improve blood flow, and reduce the risk of heart disease.

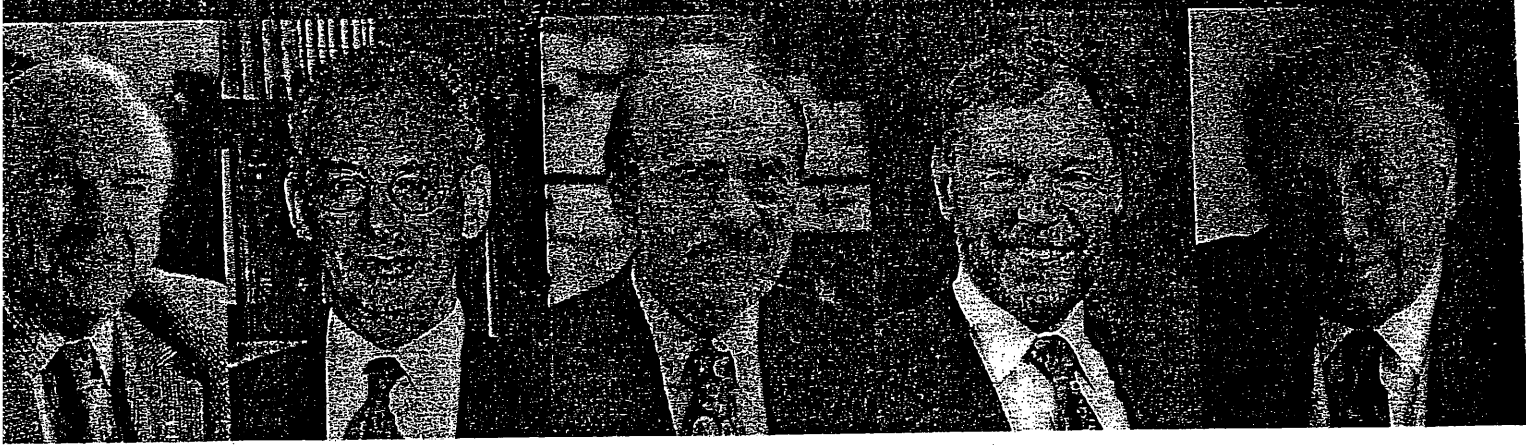


DRUG DEVELOPMENT IS WAR
ANNUAL REPORT 2000



 **United
Therapeutics**
CORPORATION
Medicines for Life™

SCIENTIFIC ADVISORY BOARD



Professor Baruch S. Blumberg, Ph.D.
1976 Nobel Laureate in Physiology or Medicine
Fox Chase Distinguished Scientist, Fox Chase Cancer Center



Professor Raymond A. Dwek, F.R.S.
Director, University of Oxford Glycobiology Institute,
Chairman of the Department of Biochemistry



Louis J. Ignarro, Ph.D.
Professor, Molecular and Medical Pharmacology
Jerome J. Belzer, M.D., Distinguished Professor of Pharmacology, UCLA
1998 Nobel Laureate in Physiology or Medicine



Lewis Rubin, M.D.
Director, Pulmonary/Critical Care Division
University of California, San Diego



Sir John Vane, D.Sc., F.R.S.
1982 Nobel Laureate in Physiology or Medicine
Chairman of the Scientific Advisory Board

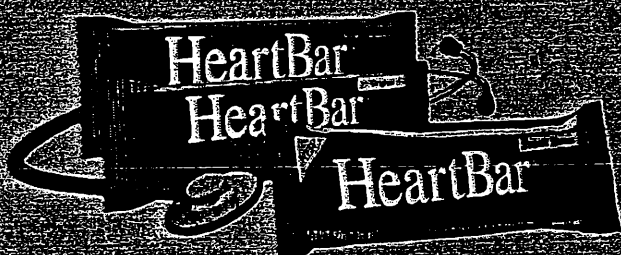


United Therapeutics benefits from having an advisory board that comprises a renowned group of experts. Chaired by the discoverers of the prostacyclin molecule, our Scientific Advisory Board includes three Nobel Laureates: Sir John Vane, D.Sc., F.R.S., co-discoverer of prostacyclin; Professor Baruch S. Blumberg, Ph.D., discoverer of the hepatitis B virus marker; and Professor Louis J. Ignarro, Ph.D., co-discoverer of nitric oxide's role in the cardiovascular system. Our Scientific Advisory Board provides valuable vision, product guidance, and industry contacts. The Board's medical acumen is provided by thought-leaders Robyn J. Barst, M.D., Professor of Pediatrics, Columbia University College of Physicians and Surgeons, Director, Pulmonary Hypertension Center, New York Presbyterian Hospital; Professor John Eric Deanfield, M.B., BChir, F.R.C.P., Senior Lecturer at St. Bartholomew's Hospital, London; Professor Raymond A. Dwek, F.R.S., Director, University of Oxford Glycobiology Institute, Chairman of the Department of Biochemistry; Professor Victor J. Dzau, M.D., Chairman of the Department of Medicine of Brigham & Women's Hospital, Harvard Medical School; Professor Salvador Moncada, M.D., Ph.D., D.Sc., co-discoverer of prostacyclin and Vice Chairman of the Scientific Advisory Board; Urban Ramstedt, Ph.D., Virus Research Institute in Cambridge, Massachusetts; Lewis Rubin, M.D., Director, Pulmonary/Critical Care Division, University of California, San Diego; and Professor Sir Magdi Yacoub, M.D., F.A.C.S., England's National Heart and Lung Institute.

HEARTBAR

HeartBar is the only medical food for the dietary management of vascular disease. Clinical studies conducted by Cooke Pharma have demonstrated the ability of the HeartBar to reduce painful symptoms associated with cardiovascular diseases as well as to increase a patient's exercise capacity and to improve quality of life scores. Cooke Pharma owns the sole patent rights to use the HeartBar's key ingredient, arginine, for cardiovascular diseases. In 1998, three American scientists received the Nobel Prize for their discovery that healthy blood vessels produce nitric oxide, which keeps blood vessels relaxed and open. The HeartBar increases the vaso-relaxing effect of nitric oxide. Randomized, double-blinded clinical

studies published in medical journals and presented at the 2000 American Heart Association meeting have shown that the HeartBar works. This year our subsidiary, Unither Pharmaceuticals, will test the ability of the HeartBar to relieve angina in a large, multi-center, well-controlled study. The HeartBar is included in the Physician's Desk Reference.



For Immediate Release
For Further Information Contact:
Therese Fergo 301-608-9292
Email Therese@unither.com

UNITED THERAPEUTICS ACQUIRING COOKE PHARMA, EXPANDING INTO ANGINA AND CORONARY ARTERY DISEASE

Silver Spring, MD and Belmont, CA, December 18, 2000 – United Therapeutics Corporation (NASDAQ: UTHR) announced today that its wholly owned subsidiary, Unither Pharmaceuticals, Inc., is acquiring all of the assets of Cooke Pharma, Inc., the exclusive maker of the HeartBar®, the first and only medical food for angina and other cardiovascular conditions. Medical foods are regulated by the FDA.

The HeartBar relieves the symptoms of heart disease by increasing the diameter of blood vessels and thereby increasing blood flow. Clinical studies conducted by Cooke Pharma have demonstrated convincingly the ability of the HeartBar to reduce painful symptoms of cardiovascular disease, increase exercise tolerance and improve the quality of life. Privately held Cooke Pharma is the only company that owns the patent rights to use the HeartBar's key ingredient, arginine, in a food product for cardiovascular diseases. Cooke Pharma sold over four million HeartBars as an over-the-counter product during 1999-2000.

The HeartBar, which is included in the Physicians Desk Reference, increases the relaxing effect of nitric oxide produced by blood vessels. In 1998, three American scientists received the Nobel Prize for their discovery that healthy blood vessels make nitric oxide, which keeps them relaxed and open. Randomized, double-blinded clinical studies published in leading medical journals and presented at the 2000 American Heart Association conference have shown that the HeartBar reduces angina and significantly improves exercise ability as compared to placebo. Cooke Pharma has other products in development based on its issued and pending patents targeting those at risk of heart disease and for overall cardiovascular health.

The Cooke Pharma Scientific Advisory Board includes two Nobel Laureates in Medicine, Sir John Vane and Dr. Louis Ignarro, as well as the Chairman of Medicine of Harvard Medical School, Dr. Victor J. Dzau, among other experts in cardiology. The founder of Cooke Pharma, Dr. John Cooke, is the Director of Vascular Medicine at the Falk Center for Cardiovascular Research at Stanford University.

"With the acquisition of Cooke Pharma's impressive technology platform, United Therapeutics gains a pioneering medical food product with dynamic growth potential in the \$13 billion heart disease market, as well as the larger market of 60 million Americans who are at risk of developing heart disease," said Dr. Barry Kanarek, President and COO of Unither Pharmaceuticals. "Cooke Pharma complements United Therapeutics' mission

to develop highly effective, clinically proven therapies to combat cardiovascular disease," Dr. Kanarek said.

The acquisition is structured as a taxable stock-for-assets purchase with a residual royalty stream. United Therapeutics will issue approximately 300,000 shares of its common stock to Cooke Pharma, subject to adjustment within a year, and Unither Pharmaceuticals agreed to pay a single-digit cash royalty to Cooke Pharma on sales of Cooke Pharma products up to an additional \$49 million, subject to possible reduction. Unither Pharmaceuticals will create a new wholly owned subsidiary which will operate under the Cooke Pharma name and will be managed by Cooke Pharma's existing management team. Closing of the asset purchase agreement is contingent upon several consents and approvals, including approval of the transaction by Cooke Pharma's shareholders by December 31, 2000.

"This transaction will create a winning combination that can benefit millions of consumers and patients who have or are at risk of developing heart and vessel disease," said John Cooke. "Both United Therapeutics and Cooke Pharma share a strong commitment to improving cardiovascular health and saving lives. We believe United Therapeutics has the vision, clinical expertise and resources to make the HeartBar and future formulations market leaders worldwide," continued Dr. Cooke.

Dr. Kanarek added, "Led by Dr. Cooke, Cooke Pharma has a respected record of combining medical science with product innovation. We expect the HeartBar could become an important weapon against heart disease."

Through his own extensive research at Stanford University, Dr. Cooke pioneered the use of arginine and other nutrients to improve vessel function and relieve symptoms in patients with peripheral vascular disease and with coronary artery disease. Dr. Cooke formulated these nutrients into medical foods and founded Cooke Pharma in 1995 to produce and market the products. The HeartBar is available over-the-counter at pharmacies nationwide. Cooke Pharma has plans to launch a second product, a drink, in 2001.

United Therapeutics is a biotechnology company focused on combating cardiovascular, inflammatory and infectious diseases with unique therapeutic products.

* * *

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents, their attorneys, and counsel for Federal Trade Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. 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,

Decision and Order

Inc., which is wholly owned by respondent United Therapeutics Corporation.

2. 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.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For purposes of this order, the following definitions shall apply:

1. “Competent and reliable scientific evidence” shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.
2. Unless otherwise specified, “respondents” shall mean United Therapeutics Corporation, Unither Pharma, Inc., and their successors, assigns, officers, agents, representatives and/or employees.
3. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
4. “Food” and “drug” shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55, and “over-the-counter” shall mean available without a prescription.

Decision and Order

5. “L-Arginine product” means any food, over-the-counter drug, medical food, or dietary supplement which contains as an ingredient the amino acid L-arginine.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of HeartBar, HeartBar Plus, HeartBar Sport (collectively “HeartBar”), or any other L-Arginine product used in or marketed for: (1) the treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, that such product:

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

unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Decision and Order

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, medical food, or dietary supplement used in or marketed for: (1) the treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function, shall not make any representation, in any manner, expressly or by implication, about the health benefits, performance, or efficacy of such product, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any food, medical food, or dietary supplement used in or marketed for: (1) the treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

IV.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

Decision and Order

V.

Nothing in this order shall prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VI.

IT IS FURTHER ORDERED that respondents shall, within thirty (30) days after the date of service of this order, send by first class certified mail, return receipt requested, to each distributor, seller, or purchaser for resale of any HeartBar product with whom respondents, or their agents, successors, or assigns, have done business since January 1, 2001, notice of this order in the form attached as Attachment A. The mailing shall not include any other documents.

In the event that respondents receive any information that, subsequent to its receipt of notice of this order, any distributor, seller, or purchaser for resale is using or disseminating any advertisement or promotional material containing claims about HeartBar prohibited by Parts I, II, or III of this order, respondents shall: (1) immediately send such distributor, seller, or purchaser for resale a letter requesting that it stop using or disseminating any such advertisement or promotional material and notifying it that any such use or dissemination will be reported to the Commission; and (2) within thirty (30) days notify the Associate Director for Advertising Practices, Bureau of Consumer Protection, Federal Trade Commission, in writing, of the identity of such distributor, seller, or purchaser for resale and its use or dissemination of any advertisement or promotional material containing claims about HeartBar prohibited by Parts I, II, or III of this order.

Decision and Order

VII.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation including videotape recordings of all such broadcast advertisements;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VIII.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, shall deliver a copy of this order to all current and future officers, directors, and managers, and to all current and future employees, and agents having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and, for a period of five (5) years after the date of service of this order, to future personnel within thirty (30) days after the person assumes such position or responsibilities.

Decision and Order

IX.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which respondents learn less than thirty (30) days prior to the date such action is to take place, respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

X.

IT IS FURTHER ORDERED that respondents, and their successors and assigns, shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

XI.

IT IS FURTHER ORDERED that this order will terminate on July 22, 2023, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes

Decision and Order

later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that the respondents did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Decision and Order

ATTACHMENT A

BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED
[To be printed on letterhead of Unither Pharma, Inc. or
United Therapeutics Corporation]

[date]

Dear [distributor, seller, or purchaser for resale]:

We write to announce Unither Pharma's new advertising policy for HeartBar related products. As you may be aware, on _____, 2003, the Federal Trade Commission ("FTC") announced a settlement and consent agreement with Unither Pharma, Inc. and United Therapeutics Corporation related to the marketing of HeartBar products. This agreement requires that the claims we make when marketing HeartBar products must be accurate and grounded in competent and reliable scientific evidence.

We are committed to obeying fully the requirements of this settlement agreement with the FTC, while, at the same time, vigorously supporting sales of HeartBar products. To better explain how this advertising policy change may affect you, we briefly summarize the agreement with the FTC and ask for your full cooperation in ensuring that HeartBar products are sold in a manner consistent with this policy.

The Settlement Agreement

In its complaint accompanying the consent order, the FTC alleged, among other things, that our advertisements made unsubstantiated claims that: (1) HeartBar substantially decreases leg pain for people with cardiovascular disease; (2) HeartBar reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, or estrogen deficiency; (3) HeartBar prevents age-related vascular problems, including "hardening of the

Decision and Order

arteries” and plaque formation, and reduces the risk of developing cardiovascular disease; (4) 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 (5) HeartBar Sport improves endurance and energy for the general population.

The FTC’s complaint further alleged that our advertisements falsely claimed that clinical studies, research, and/or trials show that: (1) HeartBar decreases angina pain, including by as much as 70% within two weeks; (2) HeartBar decreases leg pain while walking or exercising, including by as much as 66% within two weeks, for people with peripheral artery disease; (3) HeartBar reverses the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart; and (4) HeartBar Sport improves endurance and energy for the general population.

We deny the FTC’s complaint allegations and do not admit to any wrongdoing or violation of law. However, in order to resolve this matter, Unither Pharma, Inc. and United Therapeutics Corporation have entered into a settlement agreement with the FTC. Pursuant to the consent agreement, Unither Pharma, Inc. and United Therapeutics Corporation are required to request that our distributors and sellers stop using or distributing advertisements, packaging, or promotional materials containing claims challenged by the FTC. We are sending you this letter, because you are one of our distributors, sellers, or purchasers for resale.

Unless we have competent and reliable scientific evidence to support our claims, the consent agreement prohibits us from representing that any HeartBar product:

- substantially decreases leg pain for people with cardiovascular disease;
- reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, estrogen deficiency, or any

Decision and Order

other medical condition or health risk;

- prevents age-related vascular problems, including “hardening of the arteries” and plaque formation, or reduces the risk of developing cardiovascular disease;
- reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, or for medications, such as nitroglycerin, in patients with cardiovascular disease; or
- improves endurance, circulation, and energy for the general population.

The consent agreement also prohibits us from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research regarding any HeartBar product.

Our Commitment

Unither Pharma, Inc. and United Therapeutics Corporation are committed to the continued study of the health benefits of the HeartBar product and L-arginine through scientifically valid, well-controlled clinical testing. It is the companies’ hope that such testing will produce competent and reliable scientific evidence necessary to support additional claims that supplemental L-arginine provides certain health benefits. However, Unither Pharma, Inc. and United Therapeutics Corporation wish to emphasize that it is critically important that claims made pertaining to such health benefits only be made based upon such competent and reliable scientific evidence.

Your Assistance

We request your assistance in complying with the consent agreement. Please discontinue using, distributing, or relying on any of our advertising or promotional material, including

Decision and Order

packaging, for any HeartBar product that makes any of the claims mentioned above. Please also notify any of your customers who resell these products and who may have such materials to discontinue using such promotional materials. If we receive information that you are continuing to use materials that do not comply with the consent agreement, we will notify the FTC of your failure to comply with this request.

We very much look forward to our mutual continued success and thank you very much for your assistance.

Sincerely,
[name]

President
Unither Pharma, Inc./United Therapeutics
Corporation

Analysis

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Unither Pharma, Inc. and its parent company, United Therapeutics Corporation (collectively “Unither”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves allegedly misleading representations about Unither’s HeartBar products, chewy food bars and powders enriched with L-Arginine, vitamins, and minerals. HeartBar’s labeling describes the product as the only “medical food” for the dietary management of heart and vascular disease.

According to the FTC complaint, Unither failed to have substantiation for the claims that HeartBar: (1) substantially decreases leg pain for people with cardiovascular disease; (2) reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, or estrogen deficiency; (3) prevents age-related vascular problems, including “hardening of the arteries” and plaque formation, and reduces the risk of developing cardiovascular disease; (4) 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 (5) improves endurance and energy for the general population. Among other reasons, 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

Analysis

experience of a single or a few subjects account for the benefits purportedly experienced by the active group as a whole.

The complaint further alleges that, contrary to Unither's claims, clinical studies, research, and/or trials do not show that HeartBar: (1) decreases angina pain, including by as much as 70% within two weeks; (2) decreases leg pain while walking or exercising, including by as much as 66% within two weeks, for people with peripheral artery disease; (3) reverses the effects of high cholesterol, smoking, diabetes, and estrogen deficiency on the heart; or (4) improves endurance and energy for the general population.

The proposed consent order contains provisions designed to prevent the Unither from engaging in similar acts and practices in the future.

Part I of the order prohibits claims that HeartBar (HeartBar, HeartBar Plus, or HeartBar Sport), or any other L-Arginine product used in or marketed for the treatment, cure, or prevention of cardiovascular disease, or the improvement of cardiovascular or vascular function: (1) substantially decreases leg pain for people with cardiovascular disease; (2) reverses damage or disease to the heart caused by high cholesterol, smoking, diabetes, estrogen deficiency, or any other medical condition or health risk; (3) prevents age-related vascular problems, including "hardening of the arteries" and plaque formation, or reduces the risk of developing cardiovascular disease; (4) reduces or eliminates the need for surgery, such as a coronary bypass or angioplasty, or for medications, such as nitroglycerin, in patients with cardiovascular disease; or (5) improves endurance, circulation, and energy for the general population, unless the claims are substantiated by competent and reliable scientific evidence.

Part II of the order requires that Unither possess competent and reliable scientific evidence to support any future claims about the health benefits, performance, or efficacy of any food, medical food, or dietary supplement used in or marketed for: (1) the

Analysis

treatment, cure, or prevention of cardiovascular disease, or (2) the improvement of cardiovascular or vascular function. For the same products covered in Part II, Part III of the order prohibits Unither from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Parts IV and V of the order permit drug claims permitted in labeling under any tentative final or final standard promulgated by the FDA, or under any new drug application approved by the FDA, and any representation for any product permitted in labeling by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.

Part VI of the order mandates that the respondents notify their distributors as to the claims the Commission has challenged and report to the Commission any distributors who continue to make claims that the Commission's order prohibits.

Parts VII, VIII, IX, and X of the order require Unither to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, to provide copies of the order to certain of its personnel, to notify the Commission of changes in corporate structure, and to file compliance reports with the Commission. Part XI provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

SNORE FORMULA, INC., ET AL.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4090; File No. 0223247*
Complaint, July 24, 2003--Decision, July 24, 2003

This consent order, among other things, requires Respondent Snore Formula, Inc. – and its officers, Respondents Dennis H. Harris, M.D., Ronald General, and Gerald L. "Jerry" Harris, also doing business as KJ Enterprises – to possess and rely upon competent and reliable scientific evidence to substantiate representations that “Dr. Harris' Original Snore Formula” tablets – or any other food, drug, device, service, or dietary supplement – prevents sleep apnea in adult or child users who would otherwise develop sleep apnea; treats sleep apnea; or eliminates, prevents, or reduces snoring. The order also requires Respondent Harris to possess and rely upon competent and reliable scientific evidence – and an actual exercise of his represented expertise – to substantiate representations he makes as an expert endorser. In addition, the order requires the respondents to affirmatively disclose a warning about sleep apnea and the need for consultation with a physician or a specialist in sleep medicine whenever they represent that a product or service that has not been shown to be effective in the treatment of sleep apnea is effective in eliminating, preventing, or reducing snoring. The order also prohibits the respondents from providing to any person or entity “means and instrumentalities” that contain any claim about the benefits, performance, efficacy, or safety of any food, drug, device, service, or dietary supplement – unless such claim is true and substantiated by competent and reliable scientific evidence – and from making false claims about scientific support for any product or service.

Participants

For the Commission: *Jonathan Cowen, Jock Chung, J. Reilly Dolan, and Elaine D. Kolish.*

For the Respondents: *Claude Wild III and James Prochnow, Patton Boggs LLP.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Snore Formula, Inc., a corporation; Dennis H. Harris, M.D.,