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## **Drug Ads Raise Questions for Heart Pioneer**

## **By STEPHANIE SAUL**

Dr. Robert Jarvik is best known for the artificial heart he pioneered more than a quarter-century ago. Since then he had toiled in relative obscurity — until he began appearing in television ads two years ago for the <u>Pfizer cholesterol</u> drug <u>Lipitor</u>.

The ads have depicted him, among other outdoorsy pursuits, rowing a one-man racing shell swiftly across a mountain lake. "When <u>diet</u> and <u>exercise</u> aren't enough, adding Lipitor significantly lowers cholesterol," Dr. Jarvik says in the ad.

Celebrity advertising endorsements are nothing new, of course. But the Lipitor campaign is a rare instance of a well-known doctor's endorsing a drug in advertising — and it has helped rekindle a smoldering debate over whether it is appropriate to aim ads for prescription drugs directly at consumers.

A Congressional committee, concerned that the Lipitor ads could be misleading, has said it wants to interview Dr. Jarvik about his role as the drug's pitchman.

Some of the questions may involve his credentials. Even though Dr. Jarvik holds a medical degree, for example, he is not a cardiologist and is not licensed to practice medicine. So what, critics ask, qualifies him to recommend Lipitor on television — even if, as he says in some of the ads, he takes the drug himself?

And, for that matter, what qualifies him to pose as a rowing enthusiast? As it turns out, Dr. Jarvik, 61, does not actually practice the sport. The ad agency hired a stunt double for the sculling scenes.

"He's about as much an outdoorsman as <u>Woody Allen</u>," said a longtime collaborator, Dr. O. H. Frazier of the Texas Heart Institute. "He can't row."

The House Committee on Energy and Commerce is looking into when and why Dr. Jarvik began taking Lipitor and whether the advertisements give the public a false impression, according to John D. Dingell, the Michigan Democrat who is the committee's chairman.

"It seems that Pfizer's No. 1 priority is to sell lots of Lipitor, by whatever means necessary, including misleading the American people," Mr. Dingell said.

Lipitor, the world's single best-selling drug, is Pfizer's biggest product, generating sales of \$12.7 billion last year. But as it has come under competition from cheaper generic alternatives, Pfizer has used the Jarvik campaign, introduced in early 2006, to help protect its Lipitor franchise.

Pfizer spent \$258 million from January 2006 to September 2007 advertising Lipitor, according to TNS Media Intelligence. Much of that went for the Jarvik campaign.

Dr. Jarvik's office said he would not comment on the matter, referring a reporter to a statement on his company's Web site. Pfizer has defended the overall accuracy and message of the ads.

Wherever the Congressional inquiry leads, the controversy risks damaging Dr. Jarvik's credibility and undermining his real medical mission.

Until the ads returned Dr. Jarvik to the national stage, he had quietly spent much of the last two decades in his Manhattan apartment and a Midtown workshop, refining a device meant to extend the lives of <u>heart failure</u> patients.

His recent invention, the Jarvik 2000 FlowMaker, is a pump the size of a C flashlight battery that is implanted directly into an intact human heart. It has been used experimentally on nearly six dozen patients at the Texas Heart Institute.

The <u>Food and Drug Administration</u> has authorized those experiments, although Dr. Jarvik has yet to receive F.D.A. approval to sell the Jarvik 2000 for widespread use.

The product is one he began working on in the late 1980's after he left the company he cofounded to market the Jarvik 7 — the artificial heart he helped develop at the <u>University of</u> <u>Utah</u> that was being studied as a permanent replacement for failing human hearts.

Dr. Jarvik's newer device is being assembled in the workshop of his company, Jarvik Heart, on the 15th floor of an Art Deco office building on West 52nd Street. Over the years, Dr. Jarvik has received both federal grant money and private investment capital, notably from Leon C. Hirsch, the Connecticut investor who founded the United States Surgical Corporation. But Dr. Jarvik has maintained control of the small company, and several of its employees are members of his family.

Dr. Jarvik recently placed a statement on his company's Web site defending his role as the Lipitor spokesman.

"I accepted the role of spokesman for Lipitor because I am dedicated to the battle against heart disease, which killed my father at age 62 and motivated me to become a medical doctor," it said. "I believe the process of educating the public is beneficial to many patients, and I am pleased to be part of an effort to reach them."

The Jarvik campaign was rolled out the same year that <u>Zocor</u>, Lipitor's chief competitor, became available as a generic drug that is widely considered about as effective as Lipitor but is sold at a fraction of the cost.

Criticism of consumer advertising of <u>pharmaceuticals</u> flared as an issue back in 2004, when <u>Merck</u> withdrew <u>Vioxx</u>, a heavily advertised painkiller, after a clinical trial showed that it sharply increased the risk of heart attacks and strokes. The pharmaceutical industry adopted voluntary guidelines the next year suggesting that companies delay advertising new products for an unspecified period after they first reach the market.

Despite the efforts by industry and government to curb drug advertising, spending on consumer drug ads increased more than 300 percent from 1997 to 2007, when it reached about \$4.8 billion.

Mr. Dingell and Bart Stupak, another Michigan Democrat who is chairman of the committee's subcommittee on oversight and investigations, are seeking information about the Lipitor campaign from Pfizer and the F.D.A.'s advertising review department.

The committee has expressed interest in the ad that features Dr. Jarvik sculling — or appearing to scull — which ran from March through July of 2006.

A newsletter published by the Lake Washington Rowing Club in Seattle describes how one of its rowers was a stunt double in the ad for Dr. Jarvik. The sculler, a professional photographer and rowing enthusiast named Dennis Williams, was picked partly for his size and partly because, like Dr. Jarvik, he has a receding hairline, according to the newsletter, which said a crew filmed the commercial for three days at Lake Crescent, near Port Angeles, Wash.

In the ad, Mr. Williams was shown as a solitary sculler navigating an unspoiled lake. Through deft editing, he appeared to be Dr. Jarvik. But, in fact, the frames that actually included Dr. Jarvik were shot in a rowing apparatus on a platform, according to the newsletter.

The ad agency, the Kaplan Thaler Group, declined to comment, referring all questions to Pfizer.

Pfizer would not comment on the sculling ad, but defended the Dr. Jarvik campaign.

"Pfizer stands behind its consumer advertising for Lipitor and our work with Dr. Jarvik to deliver important information on managing heart health," the company said in an e-mailed statement. "Our primary concern in all of our advertising is that the tone and content are appropriate for the intended audiences, and that it will ultimately result in encouraging valuable patient/physician dialogue that can lead to appropriate treatment."

Dr. David J. Triggle, a pharmacologist at the State University of New York at Buffalo who has written about drug advertising, says a doctor's endorsement should be scrupulously honest.

"In the case of a physician of significant reputation and renown, and Jarvik is well known for his artificial heart, I think it's sending a rather dishonest message — that, he himself taking Lipitor is healthy enough to row up and down whatever stream he was rowing," Dr. Triggle said. "Since he used a body double, that's dishonesty."

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