

Group blasts Medtronic's YouTube ads

By JANET MOORE, Star Tribune

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A watchdog group charged Wednesday that Medtronic Inc. and two other medical device firms have illegally advertised their products on the popular website YouTube without warning consumers about potential complications.

The Boston-based group, the Prescription Project, called on the U.S. Food and Drug Administration (FDA) to require the companies to withdraw the videos from YouTube, including an ad promoting Medtronic's Prestige Cervical Disc.

But a Medtronic spokesman said Wednesday that its video, which was posted by a production firm hired by the company, had been pulled.

The video features a fresh-faced mother-of-two and amateur triathlete who said she experienced intense pain in her neck after two car accidents. Nonsurgical remedies failed to provide her with any relief. "I was so tired of being miserable," she said in an "interview."

She was enrolled in a clinical trial studying the safety and effectiveness of Medtronic's Prestige Cervical Disc, an artificial neck device that is an alternative to more invasive spine fusion surgery. It resulted in "renewed life for this soccer mom," according to the video's gravelly voiced narrator. The product was approved by the FDA in 2007.

"The videos raise serious questions about whether drug and device companies are using the Internet to skirt laws that safeguard consumers," Allan Coukell, director of policy for the Prescription Project, said in a prepared statement.

While direct-to-consumer ads are fairly common for prescription drugs, the practice is less widespread in the medical device industry and usually is limited to orthopedic devices such as hip and knee implants.

Still, the Prescription Project estimates that spending on device ads aimed at consumers has risen more than 60 percent, from \$119 million in 2005 to \$193 million in 2007.

Interestingly, the physician interviewed on the Medtronic video, Dr. Thomas Zdeblick, is among the spine surgeons named in an investigation by Sen. Charles Grassley, R-Iowa, into the consulting fees paid to doctors by Medtronic in an alleged attempt to buy their brand loyalty. Zdeblick, who heads the Department of Orthopedic Surgery at the University of Wisconsin-Madison, did not respond to an e-mail Wednesday seeking comment.

Other videos cited by the group included an advertisement for Abbott Laboratories' Xience drug-coated stent, a mesh tube inserted in the arteries leading to the heart to combat blockages and ward off heart attacks. Approved by the FDA in July, Xience is now the top-selling drug-coated stent in cardiology, although sales have declined since several studies showed it may lead to potentially fatal blood clots.

Jonathon Hamilton, a spokesman for Illinois-based Abbott, said the company's videos were linked to instructions detailing the stent's risks and safety information. But in the future, he said, "We will embed safety and risk information."

A spokesman for the third company cited, Michigan-based Stryker, which advertised its Cormet hip resurfacing technology on YouTube, declined to comment.

The advertising practice has raised the ire of some members of Congress, including Sen. Herb Kohl, a Wisconsin Democrat who held hearings this year to determine whether such ads properly communicate potential health risks to consumers.

Dr. Kevin Bozic, a California orthopedic surgeon who has studied direct-to-consumer advertising, testified at a September congressional hearing about the topic. He said the majority of surgeons believe that patients exposed to advertising "were confused or misinformed about the appropriate treatment for their condition, had unrealistic expectations regarding the benefits of a specific type of procedure or implant, and requested surgery or implants that were not appropriate."

In its petition to the FDA, the Prescription Project argued that advertising a medical device is potentially more harmful than advertising drugs, because an irreversible surgical procedure is often involved.

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