

## Watchdog to Abbott: Yank YouTube ads

By Mike Colias  
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(Crain's) - A watchdog group has accused Abbott Laboratories of running promotional videos for a new medical device on YouTube that skirt federally mandated safety warnings.

The Boston-based Prescription Project said Wednesday that it has filed a petition asking the U.S. Food and Drug Administration to force North Chicago-based Abbott and two other medical-device makers to remove their YouTube spots.

The group says Abbott has four videos on YouTube that promote Xience, its new drug-coated heart stent that was launched in the United States in July. The videos "contain none of the federally mandated warnings or provisions required of medical-device advertisements," the group said in a statement.

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

An Abbott spokesman did not immediately return a message seeking comment Wednesday.

Drug-coated stents prop open the heart arteries that are cleared during angioplasty procedures and release a medication to prevent re-clogging. Xience has rapidly become the U.S. leader, with marketshare approaching 30%, according to Abbott. Third-quarter sales were \$305 million.

A one-minute, 29-second YouTube video that includes an Abbott copyright illustrates how Xience works inside the blood vessel. The video doesn't mention any precautions or warnings.

Information on Abbott's Web site lists dozens of possible side effects and precautions for Xience and general heart-stent use. The device shouldn't be implanted in patients who can't take follow-up medications that prevent blood clots, for example.

The FDA, which regulates medical devices and prescription drugs, requires that manufacturers' consumer ads include disclosures of potential side effects or other warnings. An FDA spokesman didn't immediately return a call seeking comment.

The Prescription Project also has asked the FDA to require Minnesota-based Medtronic Inc. to remove a YouTube video that features a device used in back surgery. A third petition requests the agency force Michigan-based Stryker Corp. to pull its videos for a product used in hip surgeries.

A Medtronic spokesman said the company's video was posted by a third-party vendor and has been taken down, though it's unclear if the video was posted at the company's request. "Any additional video produced by, or on behalf of, Medtronic that does not comply (with FDA guidelines) will be addressed immediately," he said in a statement.

A Stryker spokesman declined to comment.