

UPDATE 1-Medical device cos set ad rules amid criticism

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By Susan Heavey

WASHINGTON, March 5 (Reuters) - The medical device industry released guidelines on Thursday to make advertisements for its products easier to understand, but critics said the voluntary effort was not enough to protect the public.

The Advanced Medical Technology Association (AdvaMed), which represents device makers, said ads for pacemakers, artificial joints and other medical devices should be easy for consumers to comprehend and not distract them from any risks associated with the products.

AdvaMed said companies should feel free to use celebrities to endorse products as long as ads in which they appear are truthful, and it said ads should be clearly communicate when actors appear in them, which goes beyond current regulations.

The U.S. Food and Drug Administration (FDA) regulates promotional materials for devices to make sure they include some information about any risks and that they are not misleading. The Federal Trade Commission (FTC) oversees ads for less serious devices such as bandages and other products that are sold over-the-counter products.

"We see a lot of value in direct-to-consumer (DTC) advertising, but you have to make sure that the information is useful and accurate," AdvaMed President and Chief Executive Steve Ubl told Reuters.

Many ads for medical devices target an aging U.S. population. Some lawmakers and advocacy groups have expressed concern about what they see as questionable practices and oversight that is not stringent enough.

"I will be paying close attention to how individual companies implement AdvaMed's strengthened policies to ensure that consumers' interests are protected," said Sen. Herb Kohl, head of the Senate's Special Committee on Aging. Last fall, Kohl called on the industry to change its advertising before Congress took legislative action, including possibly banning its ads.

Companies, including Stryker Corp (SYK.N: [Quote](#), [Profile](#), [Research](#), [Stock Buzz](#)) and Johnson & Johnson (JNJ.N: [Quote](#), [Profile](#), [Research](#), [Stock Buzz](#)), have spent hundreds of millions of dollars touting artificial knees and artery-opening heart stents.

Medical devices are also made by Medtronic Inc (MDT.N: [Quote](#), [Profile](#), [Research](#), [Stock Buzz](#)), Boston Scientific Corp (BSX.N: [Quote](#), [Profile](#), [Research](#), [Stock Buzz](#)) and St. Jude Medical Inc(STJ.N: [Quote](#), [Profile](#), [Research](#), [Stock Buzz](#)).

"Historically, there hasn't been very much medical device direct-to-consumer advertising ... However, I think you will see more DTC advertising in our space," AdvaMed's Ubl said.

Consumer groups have pressed the FDA to take a stronger stance on device ads because of concerns that such ads may give the public an exaggerated sense of potential benefits without a clear understanding of potential complications.

John Santa, who heads Consumers Union's Consumer Reports Health Ratings Center, said consumer ads are part of a larger marketing machine used to promote products and reach doctors.

He said companies using celebrities do not acknowledge that they are paid for product endorsements.

Santa said his center has called for ads for surgically implanted devices to warn of possible infection. "The device manufacturers are not forthcoming," he said.

In December, the Prescription Project petitioned the FDA over warnings in six videos on Google Inc's (GOOG.O: [Quote](#), [Profile](#), [Research](#), [Stock Buzz](#)) YouTube, including four for Abbott Laboratories' (ABT.N: [Quote](#), [Profile](#), [Research](#), [Stock Buzz](#)) XIENCE-V drug eluting stent, one for Medtronic's Prestige Cervical Disc and one for Stryker's Cormet Hip Resurfacing product.

AdvaMed's guidelines call on device makers to voluntarily submit TV commercials to the FDA, but they do not ask the FDA to sign off on them beforehand.

Ubl said that while the principles apply to all types of media, including websites and online videos, the move to submit video to the FDA does not apply to online videos posted to company-owned sites or third-party sites like YouTube.

"The guidelines do not protect consumers," said Marcia Hams, Assistant Director of the Prescription Project.

Unlike drug ads, device ads are handled separately within the agency. The drug industry released its own set of voluntary ad guidelines in 2005.

FDA's Center for Devices and Radiological Health Director Daniel Schultz told lawmakers last year that the agency was continuing to monitor device ads for false or misleading content but that it must target its resources to "violations with the greatest public health impact."

(Reporting by Susan Heavey; Editing by Dave Zimmerman, Toni Reinhold)