

Does Your Spouse Influence Your DTC Viewing Experience?

FDA Wants to Peek Into Your Bedroom

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FDA's Office of Prescription Drug Promotion (OPDP) plans to examine differences between consumers viewing prescription drug ads with a spouse versus alone.

In its Federal Register notice about the "Spousal Influence" study ("Spousal Influence on Consumer Understanding of and Response to Direct-To-Consumer Prescription Drug Advertisements"; FDA-2014-N-1819; see <http://1.usa.gov/1ttHnjo>), FDA presented this premise:

"Consumers are often thought of as individual targets for prescription drug advertisements (ads), as if they are always exposed to DTC ads individually and subsequently make judgments about advertised products on their own. However, judgments about prescription drugs portrayed in DTC ads are likely made in social contexts much of the time.

"For example, a potential consumer and his or her spouse (e.g., marital or domestic partner) may view an ad together and discuss drug benefits, side effects, and risks. These social interactions may result in unique reactions relative to consumers who view DTC prescription drug ads alone. For example, spouses may influence their partner by expressing concern about risks and side effects that might occur, or pressuring their partner to consider the drug despite its risks and side effects. These outcomes have important public health implications."

Study Design

Participants in the research study will be couples who are married or in a "marital-like living arrangement" in which one member (consumer) has asthma and the other does not (spouse).

The FDA will compare one version of an ad that depicts a low-benefit and low-risk drug with a second version that depicts a high-benefit and high-risk drug. Participants will be randomly assigned to view the ad alone or together with their spouse.

In the "together" condition, participants will view the ad with their spouse and then engage in a brief discussion together about the ad. In the "alone" condition, participants will view the ad without their spouse, take a short break, and then respond to a questionnaire consisting of questions about information in the ad.

The short break in the "alone" condition will facilitate reflection about the ad to mirror discussion engaged in by those in the "together" condition. The consumer

in the "together" condition will complete the same questionnaire administered to those in the "alone" condition, and the spouse will complete a slightly different questionnaire that assesses key measures that relate to consumer reactions.

A Missed Opportunity

Presumably, study participants will view ads for Rx drugs that treat asthma. Is the FDA missing an opportunity to learn how spouses discuss the benefits and risks in DTC ads for drugs that really matter for couples—especially older couples who are the main targets of TV drug ads?

Why not, for example, study the reaction to ads for erectile dysfunction (ED) treatment? FDA could, for example, show study participants the new Viagra TV ad that features a sexy woman encouraging men with erectile dysfunction to try Viagra (see "Oh Yeah, Baby! Show Me More!... Viagra TV Ads Like This. But Don't Let My FDA See It!"; page 2).

Perhaps such a study is not needed to learn that (1) most men probably won't hear the fair balance section of this ad, and (2) their spouses are likely to "pressure their partner to consider the drug despite its risks and side effects."

Impact on Regulation of Ads

Pharma MedTech Insights blog wondered about the impact this study might have on future DTC ad regulations:

"It remains to be seen whether FDA intends to use the results of the study to expand its review of promotional materials to include consideration of the potential influence of the promotional materials on a spouse, who will ultimately influence the consumer's treatment decisions. It's common to see drug advertisements showing a happy, healthy couple walking down a beach or playing in a back yard with grand-children. If this touching scene causes a spouse to press his or her partner to seek more information about product will that make an otherwise balanced communication misleading?"

The new Viagra ad only includes a single woman who may not even be married let alone have grand children! It used to be that Viagra ads included a man/husband and a woman/wife, but then Pfizer focused solely on virile men (see, for example, "Be a Macho Man! Ask Your Doctor for Viagra!"; <http://bit.ly/btH8Hu>). Now Pfizer has come full circle and has a Viagra ad that features all woman and no man. What does your wife think of that?

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A Viagra TV Ad Your Spouse May Not Want You to See!

Wowie zowie! Is that a roll of dimes quarters in my pocket or am I just excited to see this new Viagra DTC TV ad that features what could be a MILF?



I pity the man who can't get an erection carousing with this woman in a beach resort or even watching her on TV lounging around the beach resort telling you that "plenty of guys" have "this issue"; i.e., getting and maintaining an erection.

Of course, this Viagra ad reneges on Pfizer's pledge back in 2005 to focus more on disease awareness in its DTC advertising. But (1) Pfizer withdrew that pledge (see <http://bit.ly/1pC4CfE>), and (2) this ad, IMHO, has sufficient redeeming prurient value to make us forget all about stuff like checking my blood pressure, etc. as a potential cause of ED.

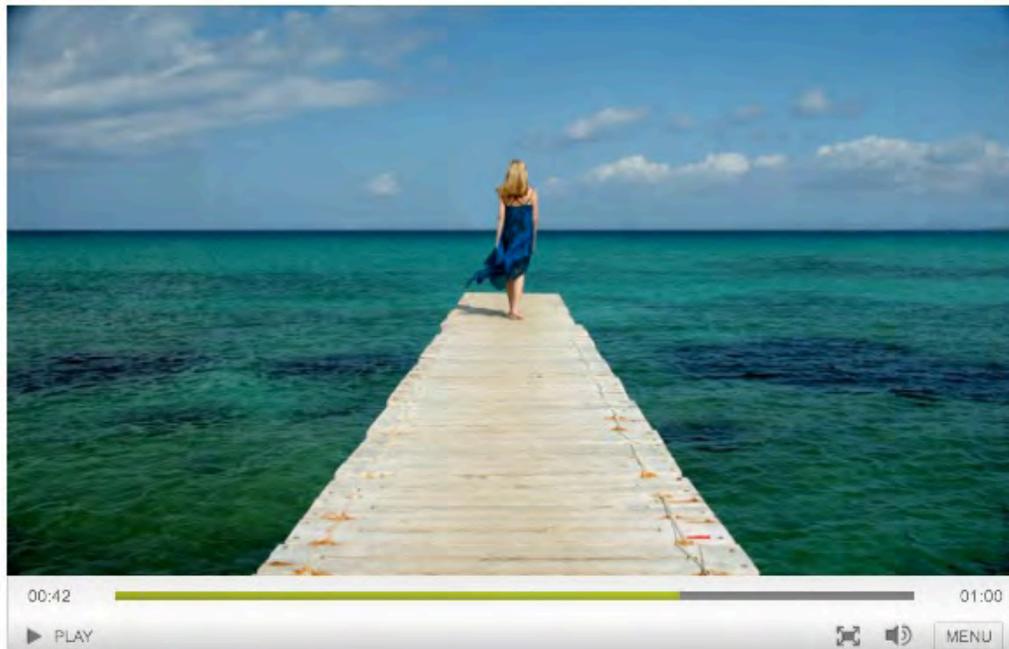
John LaMattina, former head of Pfizer R&D, thinks this new Viagra ad should be dropped. "Now perhaps there are those who won't have an issue with this ad. But it has generated a number of negative comments on social media. I believe that the biggest problem the biopharmaceutical industry faces today is restoring its reputation," said LaMattina in a Forbes Blog oped piece. If one truly believes that the industry's reputation is paramount, stop airing the new Viagra commercial" (see "New Viagra Ad Should Be Dropped"; <http://onforb.es/1CuDV2a>).

Last April, Ian Read, chairman and CEO of Pfizer, took over as the board chairman of the Pharmaceutical Research & Manufacturing Association (PhRMA). In a press release, read said: "To be successful in our purpose, we must have a reputation that ensures the full support of all segments of civil society. We are judged ultimately by our actions and we must work hard to earn the respect and trust of our regulators, legislators, healthcare professionals, R&D partners and most importantly the patients who depend on us now and in the future."

Meanwhile, continuing our review of the ad, all the "good" stuff such as Viagra "can help guys get AND keep an erection," is mouthed (and I mean lots of mouth!) by this WOMAN with a sexy British accent, whereas all the "bad" stuff such as "ask your doctor if your heart is healthy enough for sex" and "abnormal vision" is done via a voiceover in a MAN's voice. Talk about "cock blocking" dude!

Continues...

This is what you see during the voiceover citing all the required ISI (important safety information):



Obviously, she's no longer interested! The image and voiceover suggests "Nothing to see (or hear) here. Move on."

Will the FDA find problems with this ad and send Pfizer a Notice of Violation letter despite the possibility that the Agency reviewed the ad before it was aired?

FDA wants to see that the benefit and side effect portions of ads are given equal weight in terms of text, voiceovers and visuals. The FDA is trying to determine whether the use of competing, "compelling" visual information about potential drug benefits interferes with the viewers' processing and comprehension of risk information about drugs in DTC advertising or with their cognitive representations of the drugs (here). And the Agency has already cited this as violative in at least one warning letter.

I wouldn't be surprised, therefore, if doctors or key opinion leaders employed by GSK, which markets Cialis, notify FDA's BadAd program about this obvious misalignment. Obviously, any man worth his salt (or Viagra-HCL) would tune out as soon as the voiceover guy starts talking and the sexy woman walks off into the sunset.

But, you know what? Go ahead, tell the FDA. By the time FDA gets around to sending Pfizer a letter, the ad will have run its course and done its work driving "plenty of guys" to their physicians.

UPDATE: @RxRegA on Twitter wondered how much time was devoted to the woman talking about benefits versus the voice over talking about risks. Good question—it's something the FDA takes into consideration when reviewing DTC ads. So I measured what I call the MILF (benefits) to Cock Blocker (risks) ratio in this ad. MILF = 33 seconds; Cock Blocker = 24 seconds (a ratio of 1.375). That is, 38% more time is spent on benefits than on risks.

Although the voiceover is male, there are no males within eyeshot in this commercial. None of that touchy-feely, two-tub namby pamby stuff that Cialis ads feature. To paraphrase my favorite line in the movie "It's a Wonderful Life," this Viagra ad is for men who want to get hard fast and don't need props (e.g., bath tubs) around to give the ad "atmosphere"!

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