

# FDA To Change How Prescription Drugs And Biologics Are Advertised



By *Jamie Wells, M.D.* — August 25, 2017



Credit: Graphicstock [1]

Who among us hasn't chuckled at a television prescription drug ad when it ventures into a litany of wide-ranging potential side effects like anal leakage to erections lasting more than four hours? Whether it be for depression, your heart or arthritic conditions, the major and minor adverse consequences of these advertised drugs often get promoted in ways that pose equivalent risk—this routinely does not reflect reality.

With direct-to-consumer (DTC) ease of communication access today, product overstatements of health benefits with simultaneous minimization of possible harms has become the norm for such companies marketing to the public. The ability to do so wasn't always the case. With such an evolution, for better or worse, has come cultural conflicts. And, now the [U.S. Food and Drug Administration \(FDA\)](#) [2] wants to intervene to be assured the sanctity of the doctor-patient relationship is being preserved while a societal wave of unfounded fears doesn't add to risk aversion preventing a person from seeking appropriate treatment or being compliant with his medical care.

The [FDA established a public docket](#) [2] "to assist with its development of recommendations regarding the communication of risk information in direct-to-consumer (DTC) broadcast advertisements for prescription drugs and biologics." They are using the science they have procured from surveying of doctors and patients along with other research like visual tracking with dual audio and video cues to determine how individuals are challenged in acquiring information to figure out how best to proceed. Additionally, they are requesting— by November 20, 2017— data and comments from the public to help guide them.

At issue, in particular, are the current requirements for the so-called *major statement* where product claims include the advertised drug's major side effects and contraindications in the audio and/or visual components. The [FDA writes](#) [2]:

*“From a public health standpoint, FDA is interested in helping to ensure that when firms choose to advertise directly to consumers and patients, such advertisements provide clear and useful information to that audience. There is concern that the major statement, as currently implemented in DTC broadcast advertisements for prescription drugs, is not fulfilling this purpose. Some believe it is too long, which may result in reduced consumer comprehension, minimization of important risk information, and, potentially, therapeutic noncompliance caused by fear of side effects. At the same time, there is concern that DTC broadcast advertisements do not include adequate risk information or that they leave out important information.”*

The [Office of Prescription Drug Promotion \(OPDP\)](#) within FDA's [Center for Drug Evaluation \(CDER\)](#) [3] are investigating the science to drive the new policy recommendations. With a goal of getting a fair balance in the information of actual risk and drug effectiveness, these divisions are pursuing the merits of a *limited risks plus disclosure* strategy that would further classify drugs by these categories: severe risk, serious risk, and actionable risk. The accompanying disclosure could explain that the list is incomplete and a discussion with your health care provider is ideal.

Some of [the work they have already completed](#) [3] includes but is not limited to the following: determining attention and distraction of risk information in prescription drug advertising using eye tracking, examination of online DTC drug promotion, effect of promotional offers on consumer perceptions of product risks and benefits, randomized study on whether disease awareness links are misleading, health care provider and patient reactions and use of online health communities and so forth. To review their results, see [here](#). [3] This research is favoring targeted approaches to health information delivery as an optimal means to support retention, understanding and more helpful ways to weigh benefits and risks in decision-making.

Parodies— like the [Saturday Night Live \(SNL\) skit](#) [4] included above—exist for a reason. The current methods of marketing these and other biologics have exploited extremes of fear or salvation. Measured nuances are not driving the conversation. That said, when severe and extreme untoward effects are probable for a particular drug, the noise of inaccurate advertising tends to drown out such warnings while propelling them in less harmful scenarios.

Basically, a drug with legitimate and more likely ill effects should be reported as such while one of remote consequence should be as well. Nothing more, nothing less. And, these modes of communication should be reiterated to serve as information to augment your conversations with your doctor who actively is involved in your care, can even determine your personal eligibility, knows your complete medical history, has examined you and possesses a comprehensive picture of your clinical status. These ads are not in lieu of that essential relationship.

To appreciate the spot on concept of *if we don't laugh, then we might cry* over the confusion and fears these materials often generate, take a look at the [accompanying SNL video with Dwayne “The Rock” Johnson](#) [4] touting an erectile enhancement drug. The side effect profile includes hilarious gems of increasing and decreasing semen, fits of rage, stealing cars and a feeling of heat

from your heart. Due to the stringent requirements over what must be included in such ads, this clip captures the inane nature of some details while actual impacts get muted or excluded.

Tackling what should be done about how best to present information so as to be most therapeutic and realistic about concerns is a worthwhile endeavor by the FDA. It is a delicate dance, and if I would add anything to the open commentary on suggestions on how to improve consumer materials in the direct-to-consumer (DTC) prescription drug space it would start with excluding public relations and marketing professionals from writing them. In a perfect world, the scientists and physicians who performed the clinical trials along with the clinicians who actively treat patients with these agents would be able to communicate effectively for themselves and draft these messages. They are best apt to identify what the actual versus theoretical risks or absolute versus relative risks really are. What commonly occurs is as important as what does not when it comes to informing for the purposes of risk stratification. Refining these materials is a worthy task by the FDA; for, in the end, doing so best serves patients.

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[1] <http://www.graphicstock.com>

[2] <https://www.federalregister.gov/documents/2017/08/21/2017-17563/content-of-risk-information-in-the-major-statement-in-prescription-drug-direct-to-consumer-broadcast?source=acsh.org>

[3] <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm>

[4] <https://www.youtube.com/watch?v=5IZrYeUX3MI>