Most people are by now familiar with prescription drug TV ads that provide lengthy (and often confusing) laundry-list descriptions of numerous potential safety risks (seemingly regardless of the severity or likelihood of the risks). Indeed, direct-to-consumer (DTC) drug advertisements have become staple fodder for stand-up comedians and a recurring topic of Saturday Night Live skits.

It appears, however, that the days of these disclosures may be numbered. On August 18, 2017, the US Food and Drug Administration issued a notice seeking public comments related to the agency's development of recommendations for communicating risk information in DTC ads for prescription drugs and biologics. FDA's stated goal is to ensure that DTC ads provide clear and useful information for consumers and patients. FDA seeks comment on this particular topic because the agency believes that current DTC ad requirements convey either too little or too much information to consumers.

If FDA proceeds with its proposals, the television landscape may feature even more drug ads, and the advice to "talk to your doctor" will become even more important.

**What are the current FDA requirements for DTC ads?**
DTC advertising includes a broad range of print and broadcast (eg, radio and television) ads, videos, booklets, pamphlets, Internet banner ads, brochures and other materials intended for consumer viewing and that mention a specific product. All DTC ads must provide a fair balance of information about the drug's risks as compared with information about its benefits. The content and presentation of a drug's most important risks must be reasonably similar to the content and presentation of its benefits. DTC print ads must also include a "brief summary," setting out essentially all of the drug's risk information, but the print ads are not required to provide the complete approved labeling.

Current FDA policy requires branded DTC broadcast ads for prescription drugs to (1) include a "major statement" of the product's critical risk information; (2) present indications and contraindications in lay terms; and (3) make "adequate provision" for consumers to receive full FDA-approved labeling. In DTC broadcast ads, displaying or reciting the brief summary is not feasible due to the length of the brief summary and the short duration of the ad, so FDA policy permits such ads to instead provide consumers with information on how they may readily obtain the full FDA-approved labeling (i.e., "adequate provision").

However, even providing the required "major statement" for a drug in a DTC broadcast ad can present challenges, both in terms of what information must be included and in fitting all such information into the compact format of TV or radio ads. However, as FDA now notes, the typical approaches to providing the major statement may not be serving the public health goals underlying the risk disclosure requirements, and thus the agency is soliciting feedback on new approaches for risk disclosures in DTC broadcast ads.

How will the proposed changes impact information disclosed in DTC ads?

FDA is investigating the usefulness of limiting the risk disclosures required in the major statement to those that are severe, serious or actionable, along with a disclosure that alerts the audience that there are other risks associated with the product not mentioned in the ad.

As an example of language that could meet the disclosure requirement, FDA provided the following:

This is not a full list of risks and side effects. Talk to your health care provider and read the patient labeling for more information.

In this notice, FDA also provides definitions for each type of risk that should be disclosed:

- **Severe risk**: a serious risk that is life-threatening.
- **Serious risk**: the risk of reactions from using the drug that may result in inpatient hospitalization or prolonged existing hospitalization, a persistent or significant disability or incapacity or a congenital anomaly or birth defect. Reactions that do not require hospitalization, cause a disability or cause a birth defect may still be considered serious when, based on appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes previously listed.
- **Actionable risk**: a risk patients would know they have (eg, a pre-existing condition or allergy) or recognize if it occurred (eg, an observable physical or mental symptom) and can act upon to help mitigate the risk (eg, get immediate medical help to prevent a bad outcome; for example, "Stop using the product and get immediate medical help if you have swelling of the face, lips, tongue or throat").

What information is FDA looking for from stakeholders?

FDA has posed eight specific questions the agency seeks feedback on, as detailed verbatim below:

1. "What data are available regarding the impact of the current approaches to communication of risk information in DTC prescription drug broadcast advertisements on consumer comprehension of the information in the advertisement, including the impact on comprehension of product benefits and risk information?
2. What are the potential effects of only including risks from the FDA-approved product labeling that are severe, serious, or actionable (as previously defined) in the major statements of DTC prescription drug broadcast advertisements? Are there other ways of characterizing which risks should be included in the major statement? Please explain.
3. When a DTC prescription drug broadcast advertisement presents information relating to the effectiveness of a prescription drug that does not have severe, serious, or actionable risks, what types of risk could be included in the major statement?"
4. What criteria should be used to distinguish risk information that is most material to patient or consumer audiences versus risk information that is material primarily to the prescriber or other health care providers? What data are available to answer this question?

5. What criteria should be used to determine which risk information that is material to patient or consumer audiences to include in the major statement for DTC prescription drug broadcast advertisements to best protect the public health? What data are available to answer this question?

6. What is the potential impact of including (or conversely, of not including), in the major statement for DTC prescription drug broadcast advertisements, additional language that states that there are other risks not included in the advertisement while simultaneously encouraging dialogue between patients and their health care providers? (For example, additional language could include, "This is not a full list of risks and side effects. Talk to your health care provider and read the patient labeling for more information.") What data are available to answer this question?

7. What data are available on consumers' comprehension of the difference between levels (i.e., severity) of risk? Would it be in the interest of public health to include a signal before the risk information that frames and categorizes the overall level of risk associated with the product? One approach may be to include an opening statement tailored to the risk profile of the drug. For example, drugs could be divided into three defined categories and include the corresponding opening statements:

1. For drugs with severe, life-threatening risks: "[Drug] can cause severe, life-threatening reactions. These include . . . ."
2. For drugs with serious but not life-threatening risks: "[Drug] can cause serious reactions. These include . . . ."
3. For drugs with no severe or serious risks: "[Drug] can cause reactions. These include . . . ."
4. Should potential food and drug interactions be disclosed in DTC prescription drug broadcast advertisements, and if so, what criteria should be used to identify these interactions?"

Implications and takeaways

FDA's public health goal in pursuing the approaches described in the notice is to achieve greater consistency and/or uniformity in DTC ads, in hopes of allowing better comprehension and retention by consumers who view the ads and potentially take the drug. In its notice, FDA specifically noted that it is interested in helping to ensure that "such [DTC] advertisements provide clear and useful information to that audience." However, FDA further acknowledged "[t]here is concern that the major statement, as currently implemented in DTC broadcast advertisements for prescription drugs, is not fulfilling this purpose."

Based on this language, it is clear that FDA's primary goal with respect to DTC ads is to ensure consumers obtain the clearest understanding of the drug and FDA is concerned that current DTC ad requirements do not achieve that goal.

There may be additional consequences if FDA follows through on its proposals, including the following:

A new golden age of DTC advertising? Even for DTC ads for drugs without risks that fall within one of the three risk types, some risk information will still be required under FDA's longstanding requirement for fair balance communications. However, under the approaches discussed in the notice, DTC ads would likely become shorter and more streamlined. Broadcast advertising time is expensive, and for many prescription drugs, compliance with current risk disclosure requirements requires a full 60-second ad slot. To the extent that compliance with the contemplated new approach can be achieved in a 30-second ad, the cost savings may not lead to double the number of drug ads, but it is logical to predict a significant increase. More drug advertising may be broadcast both for drugs currently advertised and for other drugs whose risk profile makes broadcast advertising cost-prohibitive under the current DTC risk disclosure policies.

Shifting the safety burden with emphasis on "talk to your doctor." DTC ads for prescription drugs are different than other forms of advertising because, although they are obviously aimed at patient audiences, the product can only be acquired when a licensed healthcare practitioner prescribes the drug. This is the basis for what is commonly referred to as the "learned intermediary" doctrine, whereby the doctor makes the ultimate decision whether a drug is appropriate for any individual patient and advises the patient on how to use the drug. Thus, for prescription drugs, the physical label provided to the patient need not itself include the "adequate directions for use" that is required by law to be included on the labels of non-prescription drugs. FDA's current DTC safety disclosure policies conceptually tend to blur this distinction by requiring a level of risk disclosure that seems designed to put the burden on patients to decide whether the drug is appropriate for them before they have even asked their doctor about it. Thus, current policy is arguably in tension with the
learned intermediary doctrine and the statutory exemption for prescription drug labels to include adequate directions for use. And, as FDA itself points out, this approach may not be providing “clear and useful” information to patients.

Now, in its DTC Broadcast Notice, FDA seems willing to place a renewed emphasis and reliance on physician-patient relationships and communications to ensure the safe use of prescription drugs by lessening the DTC risk disclosure burden for DTC broadcast ads. The proposal to limit risk disclosures in DTC ads to only those that are most significant, with an added statement that there are other product risks that should be discussed with the viewer’s health care provider, illustrates this potential burden shift. FDA may not be fully ready to commit to this approach, however, and has specifically asked for comments and data on the “potential impact of including (or conversely, of not including), in the major statement for DTC prescription drug broadcast advertisements, additional language that states that there are other risks not included in the advertisement while simultaneously encouraging dialogue between patients and their health care providers?” The answers to this question may be informed and influenced by prior FDA work evaluating the impacts of DTC advertising.

In particular, in 2004, FDA published results from two surveys conducted in 1999 and 2002 on patient and physician attitudes with respect to DTC ads, and among other things, found that a declining number of patients “indicated that DTC advertising was useful in terms of their interaction with their doctor and their healthcare decision making.” However, the survey report also largely dismissed concerns that patients could not get the necessary information and advice from their doctors, noting that “for the most part, patients feel comfortable asking questions about DTC-advertised drugs,” and that “the majority of physicians agreed (73%) that because of DTC advertising, the patient asked thoughtful questions.”

Those surveys, however, were conducted in the context of FDA’s current DTC risk disclosure policies, and it will not be surprising if some stakeholders argue in comments to the docket that the survey conclusions would be inapplicable or inaccurate under the modified policies outlined in the DTC Broadcast Notice.

Commenting

As with many policy proposals in the prescription drug realm, FDA is likely to receive comments both strongly supporting and strongly opposing its proposed new approaches, which may make its ultimate decision a difficult one to reach. A final decision by FDA may not emerge for many months or even years after the comment period closes, which is on November 20, 2017.

Learn more about this development and about submitting comments to FDA by contacting the authors.