FDA Urged to Change Rules on Off-Label Use

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PHILADELPHIA — The Food and Drug Administration needs to change the way it regulates promotion of off-label drug use, according to the chair of the department of health policy and public health at the University of the Sciences in Philadelphia.

The FDA has issued draft guidance regarding off-label promotion. The draft guidance states that although any materials promoting off-label use must be peer reviewed, approval by the agency is not required, and the pharmaceutical company does not need to prove its intent to submit a new drug application for the off-label use, Robert I. Field, J.D., Ph.D., said at a meeting of the American Society of Law, Medicine, and Ethics. "This is considered to be a significant loosening of the requirements, certainly of the FDA's enforcement attitude."

However, the company must clearly disclose that the suggested use is off-label, and any published negative findings regarding the off-label use must be included in the materials. "The problem is, negative findings don't get published very often," he added.

But medicine only advances when information is shared, "and there are good reasons to allow off-label uses and therefore to allow physicians to know about those off-label uses," he said. However, "lack of oversight will lead to overzealous, aggressive promotion of uses that have limited, if any, scientific substantiation. The big question [is whether the] average physician, who's working 80 hours a week [is] really going to be able to evaluate this information, even if it has a disclosure written at the top?" ■