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FDA 2018 Year in Review: Advertising and Promotion

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Developments in 2018

In June, FDA finalized its guidance on Medical Product Communications That Are Consistent with the FDA-Required Labeling. The guidance explains how manufacturers, packers, distributors and their representatives may communicate information in promotional materials and data about approved or cleared uses of a product that are not included in the FDA-required labeling. The guidance is narrowly tailored and defines "FDA-required labeling" to include labeling reviewed and approved by FDA as part of the medical product marketing application review process. The guidance does not address off-label communications about unapproved uses.

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The guidance sets forth a three-factor test that FDA will use to determine if a drug, biological product or device firm is communicating information about its product consistent with FDA-required labeling. The factors are summarized as follows:

- Does the information provided differ from or conflict with the information about the conditions of use in the FDA-required labeling?
- Will the information in the communication increase the potential for harm to health, when compared to the information in the FDA-required labeling?
- Do the directions for use in the FDA-required labeling enable the product to be safely and effectively used under the conditions discussed in the communication?

The guidance emphasizes that communicating information in a manner consistent with FDA-required labeling is not enough to avoid an enforcement action; firms must also comply with FDA's other labeling and advertising provisions.

In June, FDA also finalized its Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities — Questions and Answers guidance, providing a clearer framework around the dissemination of information regarding prospective patient utilization and dissemination of the results of studies.

In its draft guidance Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements, FDA states that quantitative efficacy or risk information presented in direct-to-consumer promotional materials may lead to greater consumer comprehension than qualitative information. FDA offers multiple recommendations with regard to presenting quantitative efficacy or risk information in a consumer-friendly manner:

- **Use Absolute Probability Presentations:** Firms should convey information in terms of absolute frequencies (e.g., 57 out of 100) or percentages (57 percent). If relative frequency information is provided (e.g., 50 percent reduction of risk), absolute probability measures should also be provided (e.g., 50 percent reduction of risk—1 percent had a stroke compared to 2 percent in the control group).
- **Choose a Consistent Format:** Presentations should be consistent throughout a piece, frequencies

should use the same denominator (preferably a multiple of 10), and when possible, whole numbers should be used.

- **Use Appropriate Visual Aids:** Visual aids help consumer comprehension and should be carefully and clearly labelled and defined, should include information proportionate to the quantity described (bar graphs representing appropriate proportions), and should include both the numerator and denominator of ratios or frequencies.
- **Include Comparator Numbers:** Both the treatment and the control groups should be represented to improve consumer perceptions about a drug's efficacy and risk.

In 2018, CDER's Office of Prescription Drug Promotion (OPDP) issued a recent historical low number of warning letters (two) and untitled letters (five) to pharmaceutical manufacturers. Both warning letters were related to failure to present or present adequate risk information—violations that FDA cited in untitled letters as well. Notably, OPDP issued an untitled letter alleging that a manufacturer made false or misleading claims or representations about the efficacy of its product, the first of its kind since the ultimately withdrawn Pacira Pharmaceuticals warning letter.

Violations cited in the remaining untitled letters included off-label promotion (promotion of unapproved uses for an approved product), lack of adequate directions for use in labeling, and pre-approval promotion of investigational drugs. One of the warning letters and one of the untitled letters resulted from complaints submitted to OPDP's Bad Ad Program, which is designed to educate HCPs about the role they can play in helping FDA ensure that prescription drug advertising and promotion is truthful and not misleading. The Center for Device Evaluation and Research (CDER) Office of Compliance did not issue any letters related to advertising or promotion violations in 2018.

Read more on FDA 2018 Year in Review.