Stakeholders Weigh FDA Proposal to Limit Risk Info in DTC Advertisements

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Industry and pharmacy groups generally support the US Food and Drug Administration's (FDA) proposal to limit the amount of risk information presented in pharmaceutical direct-to-consumer (DTC) advertisements, though others have criticized the plan and research backing it as flawed.

Background

In August, FDA proposed (http://www.raps.org/Regulatory-Focus/News/2017/08/21/28285/FDA-Weighs-Limited-Risk-Info-in-DTC-Ads/) a new approach to presenting risk information in DTC television and radio ads that would allow drugmakers to limit the amount of risks presented.

Currently, DTC drug ads must present a product's major risks alongside its benefits to ensure a "fair balance" of information in what's known as a "major statement," but FDA and others have conducted research raising concerns that the risk statements in DTC ads are too long and can result in consumers not understanding or minimizing the importance of a product's risks.

Under the new approach, FDA would allow drugmakers to limit the risks listed in broadcast ads to severe (life-threatening), serious or actionable risks, and require that the ad include a disclosure that not all risks were included, such as "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."

The August announcement followed the release of a study by FDA officials (http://raps.org/Regulatory-Focus/News/2017/08/07/28190/FDA-Officials-Study-Alternative-Approach-to-Presenting-Risk-Info-in-TV-Drug-Ads/) suggesting that presenting limited risk information in DTC television ads could improve consumers' ability to recall those risks.

Comments

In comments released last week, 53 stakeholders weighed in on FDA's proposal, including the industry lobbying group PhRMA, drugmaker Eli Lilly, the Academy of Managed Care Pharmacy (AMCP) and Public Citizen's Health Research Group.

PhRMA said it "supports a 'limited risks plus disclosure' strategy for the 'major statement,'" as "data demonstrate that the current FDA format may be too long and complex for most, if not all, broadcast advertisements and result in: (1) reduced consumer comprehension; (2) over warning leading to the minimization of the most important risk information; and (3) potentially, therapeutic noncompliance because of fear of side effects."

However, PhRMA recommends that any "limited risks plus disclosure" strategy focus only on those risks that are "serious and actionable."

But the lobbying group disagreed with what it calls a shift in FDA's approach to its strategy, saying it goes too far.

FDA "appears to support a model under which DTC broadcast advertisements would include risks that are 'severe (life-threatening), serious, or actionable.' The Agency has not provided an explanation or justification for this shift in its approach," PhRMA said. "The new proposed formulation broadens the 'limited risks' that would be covered in the 'major statement' to those that are: (1) non-serious although actionable, and (2) non-actionable although serious/severe. Such an approach would undermine some of the benefits of the 'limited risks plus disclosure' strategy, including by adding risks for which there is not some action a patient can take to avoid or mitigate."

PhRMA also called on FDA to issue new clarifying regulations and create an "enhanced advisory comment process," with respect to establishing any "limited risks plus disclosure" strategy.

Similarly, Eli Lilly said FDA's proposal to use the three distinct categories of risk "is both prescriptive and not in service of patients," and the drugmaker seeks "a more flexible method of signaling which could employ language regarding severity of a particular warning or risk as derived from the FDA-approved product labeling for use in the 'major statement.'

"Utilizing broad risk categorizations to lump products with vastly different benefit and risk profiles may encourage consumers to view all risks that follow as impacting them in the same manner, when what would serve patients best is evaluating each risk disclosure in light of their own health status and risk tolerance," Lilly said.

In contrast to PhRMA and Lilly, the nonprofit policy group Public Citizen said FDA's proposal to decrease the amount of risk information disclosed "is fundamentally incomplete and flawed and does not address more important factors already known to affect the comprehension and recall of risk information disclosed in DTC broadcast ads."

Public Citizen also called on FDA to heighten its enforcement of existing regulations around DTC ads, including "issuing far more warning and notice of violation letters to pharmaceutical manufacturers for violative ads (broadcast or otherwise) and, for the first time ever, begin issuing civil monetary penalties to such manufacturers."

Meanwhile, AMCP said FDA's proposal is "a step in the right direction to present a fair balance of risk information to avoid a misleading presentation regarding a drug's risk-benefit profile," though the group said risk information "should be presented in a manner that: a. Uses plain language; b. Limits information to 3-5 key points; c. Is specific and concrete, not general; d. Demonstrates using pictures and models that are applicable to the information being presented; and e. Repeats and summarizes the information."

Comments (https://www.regulations.gov/docket?D=FDA-2017-N-2936)

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