Medical device crowdfunding and preapproval promotion: Where does FDA draw the line?

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The medical device industry has long sought more comprehensive guidance from the Food and Drug Administration (FDA or the agency) regarding the line between appropriate and inappropriate preapproval communications. Industry seeks clarity to be able to confidently navigate communications in the preapproval stage without running afoul of the prohibition against promotion and commercialization of uncleared/unapproved medical devices. The emerging practice of crowdfunding medical devices raises new issues about what constitutes preapproval promotion, and where the line for permissible communications might fall.

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