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Client Alert

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FDA Finalizes Guidance on Presenting Quantitative Efficacy and Risk Information in DTC Promotion

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On June 28, 2023, the U.S. Food and Drug Administration ("FDA") issued final guidance on *Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer (DTC) Promotional Labeling and Advertisements* ("Quantitative Information Guidance").[1] This action finalizes the draft guidance from 2018[2] with few substantive changes to clarify considerations for various media types and provide additional explanations regarding specific concepts and examples.

The Quantitative Information Guidance describes principles and recommendations for how to present quantitative efficacy or risk information in DTC promotional communications for prescription human drug and biological products and prescription and over-the-counter animal drugs. "Quantitative efficacy or risk information" refers to information that numerically addresses the likelihood or magnitude of a drug's efficacy or risks.[3] "When compared to *qualitative* descriptions of efficacy and risk information, *quantitative* information can improve consumers' accuracy in estimating the drug's benefits and risks."[4] Although companies "generally have flexibility regarding how they present [quantitative] information" (provided it is truthful, not misleading, and complies with other applicable legal requirements), FDA encourages companies to follow the principles and recommendations in the final guidance to help support accurate consumer understanding and perceptions about their drugs.[5]

Because the final guidance applies to the continuum of DTC promotional communications, FDA advises that companies should consider the amount of space and/or time of the specific promotional media type (*e.g.*, print, electronic, audiovisual, etc.) to determine how to best present quantitative efficacy or risk information.[6] Finally, FDA signals that the final guidance is not limited to the quantitative presentation of efficacy and risk information. Companies may apply the principles and recommendations

in the final guidance to inform quantitative presentations of other product benefits, beyond efficacy and risk information.[7]

RECOMMENDATIONS FOR QUANTITATIVE EFFICACY OR RISK INFORMATION IN DTC PROMOTION

Based on current research findings related to communicating health information, the final guidance outlines FDA's current thinking and recommendations for making the language and presentation of quantitative efficacy or risk information more consumer friendly. The following summarizes these recommendations and highlights changes from the draft guidance:

- Quantitative Efficacy or Risk Information From Both the Control Group and Treatment Group

  Quantitative efficacy or risk information should include information for both the treatment group and the relevant control group, where applicable.[8] This comparison "improves consumers' ability to process and comprehend the drug's benefits and risks and can lead to more informed decision making."[9] DTC promotional communications that include control group information should accurately describe the comparator used in the control group.[10]

- Probability Presentations

  To help improve consumer comprehension and recall, probability presentations should communicate information in terms of *absolute* frequencies (*e.g.*, 57 out of 100) or percentages (*e.g.*, 57%).[11] For example: "In a clinical trial, 78 out of 100 patients experienced a response after 12 weeks of treatment with Drug X, compared to 20 out of 100 patients on placebo."[12] Conversely, *relative* frequencies (*e.g.*, 33% reduction in symptoms) are more difficult for consumers to understand.[13] Thus, the final guidance discourages the use of relative frequency statements and recommends that if relative frequencies are used, the statement should be accompanied by the absolute probability measure, and these should appear with equal prominence. For example: "In a clinical trial, Drug X reduced the risk of stroke by 50% (1% of patients treated with Drug X had a stroke, compared to 2% of patients in the control group)."[14]

- Formatting Quantitative Efficacy or Risk Information

  Presentations of quantitative efficacy or safety information should appear in the same numerical format throughout a promotional piece, use frequencies with the same denominator and consider using denominators that are multiples of 10, and express probabilities as whole numbers, when appropriate.[15] The final guidance clarifies that quantitative probability information about a particular risk should not minimize the severity of the risk, focus attention on the low probability of serious risk, or characterize the probability of the risk as insignificant or unimportant.[16] As an example, the final guidance advises the term "only" should not be used to qualify a description about risks (*e.g.*, "In a clinical trial, *only* 2% of patients experienced bleeding that required hospitalization"), as "only" suggests that the risk is not important and may undermine the serious nature of the risk.[17]

- Visual Aids

  Because visual representations can improve consumer comprehension of numeric values, FDA recommends that companies select a visual aid design that best communicates the quantitative efficacy or risk information being presented (*e.g.*, a bar graph for comparisons between probabilities or a line graph for illustrating changes over time).[18] In addition, the final guidance includes the following general recommendations for designing visual aids:

  — Explain the purpose and elements of the visual aid clearly and accurately (*e.g.*, include a title, header, and/or caption, identify variables, scales, and axes);

  — Make visual displays of numeric information proportionate and scaling of axes appropriate to the quantities and sizes described (*e.g.*, scaling of the y axis should ensure the difference in heights between bars is proportional to the difference in values); and

— Include visual representations of both the numerator and denominator of ratios or frequencies (*e.g.*, an icon array or graph depicting an absolute frequency should represent the people who experienced the effect (numerator) and the total people studied for the effect (denominator)).[19]

CONCLUSION

The Quantitative Information Guidance seeks to ensure accurate consumer understanding with regard to quantitative information about the benefits and/or risks of a drug. These principles and recommendations are not substantially different from the draft guidance; however, the final guidance provides helpful clarity for quantitative efficacy and risk information in DTC promotion. Execution of such presentations consistent with the recommendations in the final guidance will help ensure that promotional communications are not false or misleading.

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King & Spalding LLP regularly counsels pharmaceutical and biologics companies on all issues related to advertising and promotion. Please let us know if you have any questions or concerns regarding this final guidance, or if we can be of any assistance applying this guidance to your DTC promotional communications.

[1] U.S. Food & Drug Admin., *Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements: Guidance for Industry* ("Quantitative Information Guidance") (June 2023), https://www.fda.gov/media/169803/download.
[2] U.S. Food & Drug Admin., *Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements: Draft Guidance for Industry* (Oct. 2018), https://downloads.regulations.gov/FDA-2018-D-2613-0002/attachment_1.pdf.
[3] Quantitative Information Guidance, at 1.
[4] *Id.* at 3 (emphasis added) (citations omitted).
[5] *Id.* at 2.
[6] *Id.* at 3.
[7] *Id.* at 1 n.2.
[8] *Id.* at 3–4.
[9] *Id.* at 4 (citations omitted).
[10] *Id.*

[11] *Id.*
[12] *Id.* at 4–5.
[13] *Id.* at 5.
[14] *Id.* at 5–6.
[15] *Id.* at 6 (citations omitted).
[16] *Id.*
[17] *Id.* at 7–8.
[18] *Id.* at 8.
[19] *Id.* (citations omitted).