POV: FDA Guidance on Sharing Quantitative Data in DTC Promotion

INTOUCH GROUP™

Executive Summary

On October 16, 2018, the Food & Drug Administration (FDA) released a new draft guidance titled *Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements*. This guidance provides recommendations to marketers of prescription drugs, biologics, and veterinary medicines about how to present benefit and risk information to consumers in promotional materials. The recommendations are not binding, and do not create any new obligations for marketers. This guidance does, though, give useful direction for ways to improve patient understanding of promotional claims.[1] The FDA is accepting comments and suggestions on the draft guidance for 60 days.

In light of this guidance, Intouch Group recommends that marketers of prescription products take the following steps:

01. Review existing practices and policies for presenting quantitative information in DTC promotion.

02. Update practices and policies (as needed) to reflect FDA's recommendations.

03. Evaluate existing and in-development promotional materials against the guidance recommendations.

Guidance Overview

This guidance does not change any existing requirements for promotional materials. The guidance represents a growing trend in recent FDA guidances of drawing heavily on the work from the social science team within the Office of Prescription Drug Promotion about how people (consumers and healthcare professionals) understand promotional communications.[2]

GUIDANCE SCOPE

The guidance covers advertising and promotional labeling across all media (print, broadcast, electronic, etc.)[3] and was issued by the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Veterinary Medicine.[4] Consequently, its scope covers advertising and promotional labeling for human and non-human animal prescription drugs, biologics, vaccines, and over-the-counter animal drugs.[5] Notably, the Center for Devices and Radiological Health (CDRH) is not a signatory to this guidance, so its scope does not extend to medical device promotion regulated by CDRH, though medical device manufacturers might want to consider whether and how the recommendations in this guidance apply to their communications.

GUIDANCE RECOMMENDATIONS

The guidance recommendations cover four topics regarding the presentation of quantitative information[6]:

- How and when to present absolute frequencies, percentages, and relative frequencies
- Formatting
- Using visual presentations
- Presenting treatment and control group information

Absolute frequencies, percentages, and relative frequencies

The guidance recommends that absolute frequencies or percentages be used to present quantitative information rather than relative frequencies because "[r]esearch suggests that consumers do not understand relative frequencies... as easily as they understand" absolute frequencies or percentages.[7]

We will use fictional drugs GluViva and Dexliven in our examples. Absolute frequencies are presentations of information such as "78 out of 100 patients experienced a response after 12 weeks of treatment with GluViva."[8] The corresponding percentage presentation would be, "78% of patients experienced a response after 12 weeks of treatment with GluViva." FDA notes that such presentations enable consumers to "more easily process and evaluate the information than when the same information is in a format that requires them to perform a calculation to interpret the probabilities."[9]

✓ ABSOLUTE FREQUENCY

78%

of patients experienced a response after 12 weeks of treatment with GluViva

✓ ABSOLUTE FREQUENCY

78 out of 100

patients experienced a response after 12 weeks of treatment with GluViva

By contrast, a relative frequency presentation would be a statement such as, "Consumers taking GluViva are three times as likely to experience a side effect as those taking Dexliven."[10] FDA's concern about relative frequency presentations is that consumers find them "harder to comprehend and more favorable as compared to the absolute frequency, which could lead to consumers' over- or underestimating how well the drug works or the magnitude of the risk associated with the drug."[11]

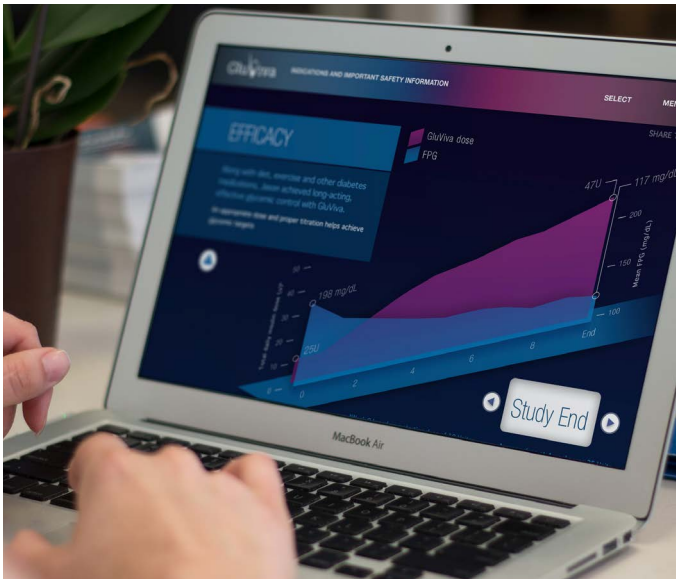
⊗ RELATIVE FREQUENCY

Consumers taking GluViva are

3X

as likely to experience a side effect as those taking Dexliven

Note that the guidance does not *prohibit* the presentation of relative frequency. Should a firm choose to present quantitative information via relative frequency, FDA recommends that firms provide context for that information, such as the underlying absolute probabilities on which the relative frequency claim is based.[12] For example, "In a clinical trial, GluViva reduced the risk of stroke by 50% (1% of patients treated with GluViva had a stroke, compared to 2% of patients in the control group)."[13]



Formatting

The guidance provides three recommendations regarding the formatting of quantitative information:[14]

01. Present the information consistently throughout the piece. Do not alternate between qualitative and quantitative presentations of similar information.[15]

02. Keep to the same denominator throughout a presentation with absolute frequencies, and try to use "denominators that are multiples of 10."[16]

03. Avoid fractions and decimals whenever possible, though if a decimal presentation is necessary, then avoid rounding the numbers in ways that could be misleading, such as when two numbers are very close or when the value is less than one.[17]

One example provided in the guidance illustrates the application of these principles as follows:

> In patients treated with GluViva, 9 out of 10 patients experienced moderate symptom relief, compared to 3 out of 10 patients who received placebo. Alternatively: In patients treated with GluViva, 90% of patients experienced moderate symptom relief, compared to 30% of patients who received placebo.[18]

PROPER FORMATTING

Moderate Symptom Relief in Patients

90%	30%
GluViva	Placebo

IMPROPER FORMATTING

Moderate Symptom Relief in Patients

90%	1/3
GluViva	Placebo

Using visual presentations of quantitative information

The FDA is generally positive about the use of visual aids to present quantitative information, noting that "[v]isual representations of efficacy and risk in DTC promotional materials improve consumer comprehension."[19] If a marketer chooses to use visuals (such as charts or graphs) to present quantitative risk or benefit information, the FDA recommends adopting the following principles:

01. "Explain the purpose of the visual aid clearly and accurately, and define the elements displayed."[20]

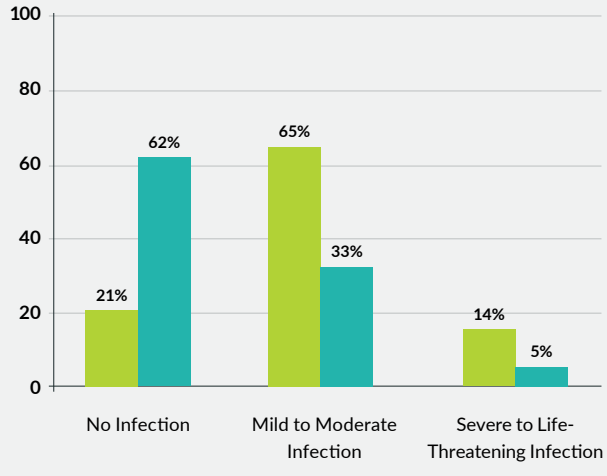
02. "Make visual displays of numeric information proportionate to the quantity being described.... For example, the height of a bar on a bar graph should be proportionate to the quantity it represents."[21]

03. "Include visual representations of both the numerator and denominator of ratios or frequencies."[22]

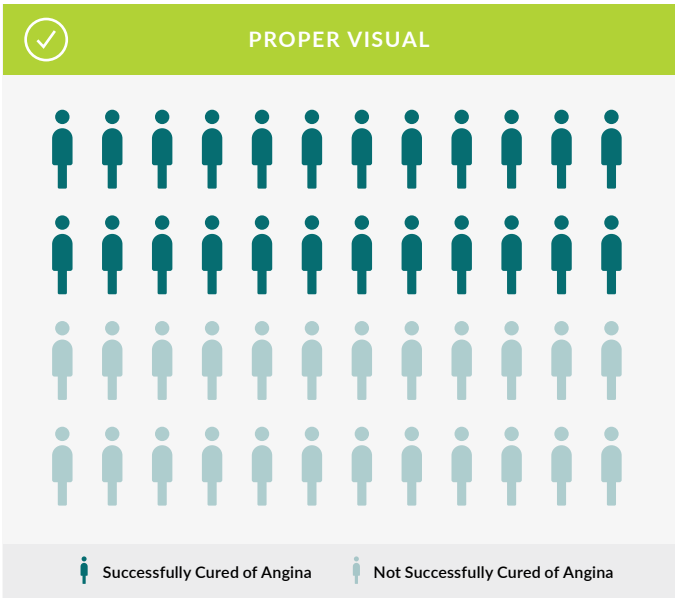
FDA provides one example illustrating the application of the principles for visual displays: a bar chart showing the comparison of patients receiving treatment with those in the control group (shown below).

PROPER VISUAL

Percentage of Patients Who Experience Infection After Treatment With GluViva Compared to Placebo



FDA cites another example showing that "icon arrays" (shown below) are an effective way to illustrate the numerator and denominator in visual presentations.[24]



Conclusion

FDA mentions in the Background section of this draft guidance that its issuance was — at least in part — a response to an apparent increase in the presentation of quantitative information in DTC promotion.[25] Many of the recommendations in this guidance will be familiar to people already working in the fields of art direction and graphic design, especially for those focused on presenting significant clinical trial data to healthcare professionals. The release of this guidance represents an opportunity to see many of the same concepts applied to the realm of DTC promotional communications.

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[1]FDA, *Presenting Quantitative Efficacy and Risk Information in Direct-to-Consumer Promotional Labeling and Advertisements*, available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM623515.pdf, last accessed Oct. 21, 2018 (hereinafter Quantitative Guidance).
[2]Among the references cited in this guidance, at least five are primarily written by staff from the OPDP research staff. Quantitative Guidance, 9-10.
[3]Quantitative Guidance, 2.
[4]Quantitative Guidance, ii.
[5]Quantitative Guidance, 1.
[6]Quantitative Guidance, 2.
[7]Quanitative Guidance, 4.
[8]Quanitative Guidance, 4.
[9]Quanitative Guidance, 3.
[10]Quanitative Guidance, 4.
[11]Quanitative Guidance, 4.
[12]Quanitative Guidance, 4.
[13]Quanitative Guidance, 4.
[14]Quanitative Guidance, 5.
[15]Quanitative Guidance, 5.
[16]Quanitative Guidance, 5.
[17]Quanitative Guidance, 5.
[18]Quanitative Guidance, 5-6.
[19]Quanitative Guidance, 6.
[20]Quanitative Guidance, 7.
[21]Quanitative Guidance, 7.
[22]Quanitative Guidance, 7.
[23]Quanitative Guidance, 7.
[24]Ancker, JS, Y Senathirajah, R Kukafka, and JB Starren, 2006, Design Features of Graphs in 307 Health Risk Communication: A Systematic Review, *J Am Med Inform Assoc*, 13(6):608–618.
[25]Quanitative Guidance, 2.

Want to learn more about the FDA Guidance?
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