
1 Presenting Quantitative
2 Efficacy and Risk
3 Information in
4 Direct-to-Consumer (DTC)
5 Promotional Labeling and
6 Advertisements
7 Guidance for Industry

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12 U.S. Department of Health and Human Services
13 Food and Drug Administration
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19 Advertising

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23 See additional PRA statement in section IV of this guidance.
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27 Presenting Quantitative Efficacy
28 and Risk Information in
29 Direct-to-Consumer (DTC)
30 Promotional Labeling and
31 Advertisements
32 Guidance for Industry

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TABLE OF CONTENTS

70
71
72
73
74 **I. INTRODUCTION.....1**
75 **II. BACKGROUND.....2**
76 **III. RECOMMENDATIONS FOR PRESENTING QUANTITATIVE EFFICACY AND**
77 **RISK INFORMATION IN DIRECT-TO-CONSUMER PROMOTIONAL LABELING**
78 **AND ADVERTISEMENTS.....3**
79 **A. Quantitative Efficacy or Risk Information From the Control Group.....3**
80 **B. Probability Presentations.....4**
81 *1. Absolute Frequencies and Percentages.....4*
82 *2. Relative Frequencies.....5*
83 **C. Formatting Quantitative Efficacy or Risk Information.....6**
84 **D. Visual Aids.....8**
85 **IV. PAPERWORK REDUCTION ACT OF 1995.....9**
86 **REFERENCES.....11**
87

88 **Presenting Quantitative Efficacy and Risk Information in Direct-to-**
89 **Consumer (DTC) Promotional Labeling and Advertisements**
90 **Guidance for Industry¹**
91

92 This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on
93 this topic. It does not establish any rights for any person and is not binding on FDA or the public. You
94 can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.
95 To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the
96 title page.
97

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101
102 **I. INTRODUCTION**
103

104 This guidance provides recommendations for presenting quantitative efficacy and risk
105 information² in direct-to-consumer (DTC) promotional labeling and advertisements for
106 prescription human drug and biological products and prescription animal drugs and in DTC
107 promotional labeling for over-the-counter animal drugs³ (collectively, *promotional*
108 *communications*).⁴ For the purposes of this guidance, quantitative efficacy and risk information
109 refers to information that numerically addresses the likelihood or magnitude of a drug's efficacy
110 or risks.
111

1 ¹ This guidance has been prepared by the Office of Prescription Drug Promotion in the Center for Drug Evaluation
2 and Research in consultation with the Center for Biologics Evaluation and Research and the Center for Veterinary
3 Medicine at the Food and Drug Administration.
4

5 ² While this guidance focuses on quantitative presentations of efficacy and risk information, firms may wish to refer
6 to the principles and recommendations for quantitative presentations of other product benefits (keeping in mind that
7 any such presentation of other product benefits otherwise must comply with applicable statutory and regulatory
8 requirements).
9

10 ³ The term *drugs* in this guidance refers to prescription human drug and biological products and to prescription and
11 over-the-counter animal drugs.
12

13 ⁴ *Promotional labeling* is generally any labeling other than the FDA-required labeling. Promotional labeling can
14 include printed, audio, or visual matter descriptive of a drug that is disseminated by or on behalf of that drug's
15 manufacturer, packer, or distributor (21 CFR 202.1(l)(2)). The Federal Food, Drug, and Cosmetic Act (FD&C Act)
16 does not define what constitutes an *advertisement* for a prescription drug, but FDA regulations provide several
17 examples (21 CFR 202.1(l)(1)).
18

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112 The guidance outlines FDA’s recommendations for how firms⁵ that include quantitative efficacy
113 or risk information in DTC promotional communications for their drugs can make the language
114 and presentation more consumer-friendly.⁶ The guidance covers the following topics:

- 115
- 116 • Providing quantitative efficacy or risk information for the control group, when applicable
- 117
- 118 • Presenting probability information in terms of absolute frequencies, percentages, and
- 119 relative frequencies
- 120
- 121 • Formatting quantitative efficacy or risk information
- 122
- 123 • Using visual aids to illustrate quantitative efficacy or risk information
- 124

125 In general, FDA’s guidance documents do not establish legally enforceable responsibilities.
126 Instead, guidances describe the Agency’s current thinking on a topic and should be viewed only
127 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
128 the word *should* in Agency guidances means that something is suggested or recommended, but
129 not required.

130

131 **II. BACKGROUND**

132

133 Under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA’s implementing
134 regulations, drug promotional labeling and prescription drug advertising must be truthful and
135 non-misleading, convey information about the drug’s efficacy and its risks in a balanced manner,
136 and reveal material facts about the drug.⁷ Firms generally have flexibility with respect to the
137 presentation of efficacy and risk information about their products as long as the presentation is
138 not false or misleading and complies with other applicable statutory and regulatory requirements.
139 When firms develop DTC promotional communications, they should consider how to best
140 convey information about a drug’s efficacy and risks so the audience understands the
141 information. This includes consideration of whether to provide efficacy and risk information by
142 using words, numbers, or visual aids, or a combination of these elements.

143

144 FDA has observed an increase in quantitative presentations of efficacy and risk information in
145 DTC promotional communications submitted to the Agency. Research on the communication of
146 treatment information suggests that consumers can recall and comprehend efficacy and risk

19 ⁵ The term *firms* in this guidance refers to manufacturers, packers, and distributors of prescription drugs (as
20 described in this guidance) and over-the-counter animal drugs, including their representatives.

21

22 ⁶ This guidance is not intended to describe whether or when a presentation of quantitative efficacy or risk
23 information would be truthful or non-misleading. FDA reminds firms that they are responsible for ensuring that
24 their promotional materials are truthful and non-misleading and that they comply with applicable statutory and
25 regulatory requirements. See, for example, sections 201(n) and 502(a) and (n) of the FD&C Act (21 U.S.C. 321(n),
26 352(a) and (n)); 21 CFR 1.21(a) and 202.1(e)(5). Additionally, we note that there may be ways other than the
27 recommendations provided in this guidance that would make presentations of quantitative efficacy or risk
28 information consumer-friendly.

29

30 ⁷ See sections 201(n) and 502(a) and (n) of the FD&C Act (21 U.S.C. 321(n), 352(a) and (n)); 21 CFR 1.21(a) and
31 202.1(e)(5).

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147 information when it is provided quantitatively (Buchter et al. 2014; O’Donoghue et al. 2014b;
148 Schwartz et al. 2007; Schwartz et al. 2009; Sullivan et al. 2015; Sullivan et al. 2019; Trevena et
149 al. 2013; West et al. 2013; Woloshin et al. 2004). When compared to qualitative descriptions of
150 efficacy and risk information, quantitative information can improve consumers’ accuracy in
151 estimating the drug’s benefits and risks (Sullivan et al. 2015; West et al. 2013). This is due in
152 part to how consumers differ in their interpretations of qualitative descriptors (e.g., *rare*,
153 *common*, *most*) and how the context in which qualitative terms are presented can affect how
154 consumers understand them (Buchter et al. 2014; Fagerlin et al. 2007; Lipkus 2007; Visschers et
155 al. 2009). Quantitative efficacy or risk information may offer more precision than qualitative
156 information; therefore, consumers can use quantitative efficacy and risk information to form
157 more accurate perceptions about the drug (Lipkus 2007).

158
159 DTC promotional communications containing quantitative efficacy or risk information should be
160 accurate and understandable. FDA recognizes that firms may experience challenges when
161 determining how to present this kind of quantitative information in DTC promotional
162 communications. For these reasons, FDA is issuing this guidance to provide recommendations
163 for presenting quantitative efficacy and risk information in DTC promotional communications
164 and to encourage firms to follow these recommendations when including such information in
165 their DTC promotional communications.

166
167 The recommendations in this guidance generally apply to quantitative efficacy and risk
168 presentations in DTC promotional communications across various media types (e.g., print,
169 electronic, audiovisual). Firms should consider the amount of space or time available and any
170 other factors specific to the media type in which their presentation will appear when determining
171 how to present quantitative efficacy or risk information in their DTC promotional
172 communications so that consumers have an opportunity to attend to and understand it.

173
174 The examples in this guidance are intended to illustrate recommended approaches to presenting
175 quantitative efficacy and risk information in DTC promotional communications. Each example
176 is meant to address a specific concept described in the guidance; a given example may not
177 illustrate every recommendation outlined. The examples do not encompass every potential
178 promotional scenario or consideration and do not necessarily reflect an evaluation of a complete
179 promotional piece, including whether the piece complies with other applicable requirements. All
180 recommendations discussed in this guidance should be taken into consideration even if not
181 expressly illustrated in an example.

182 183 184 III. RECOMMENDATIONS FOR PRESENTING QUANTITATIVE EFFICACY AND 185 RISK INFORMATION IN DIRECT-TO-CONSUMER PROMOTIONAL 186 LABELING AND ADVERTISEMENTS

187 188 A. Quantitative Efficacy or Risk Information From the Control Group

189
190 When a study includes a control group, firms that provide quantitative efficacy or risk
191 information about a drug in DTC promotional communications should provide quantitative
192 information from both the treatment group and the relevant control group. Information from the

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193 control group plays an important role in evaluating a drug’s benefits and risks (O’Donoghue et
194 al. 2014a). Including quantitative benefit or risk measures observed in the control group when
195 providing corresponding quantitative measures observed in the treatment group improves
196 consumers’ ability to process and comprehend the drug’s benefits and risks and can lead to more
197 informed decision making (O’Donoghue et al. 2014a; Schwartz et al. 2009). Research suggests
198 that consumers can use the information about the control group to form accurate perceptions
199 about a drug’s benefits (including efficacy) and risks (O’Donoghue et al. 2014a; Schwartz et al.
200 2009; Sullivan et al. 2013). Promotional communications that include control group information
201 should accurately describe the comparator used in the control group.

202
203 Example⁸ 1: In a clinical trial of 173 participants, 68% of patients who were treated with Drug
204 X plus a sulfonylurea experienced a reduction in blood glucose levels, while 33%
205 of patients treated with a sulfonylurea alone experienced a reduction in blood
206 glucose levels.

207
208 The firm is developing a social media web page for Drug X and includes a
209 presentation that 68% of patients treated with Drug X plus a sulfonylurea
210 experienced a reduction in blood glucose levels.

211
212 To improve consumers’ ability to comprehend the drug’s effect on blood glucose
213 levels, *the firm should also include that 33% of patients treated with a*
214 *sulfonylurea alone experienced a reduction in blood glucose levels.*

B. Probability Presentations

215
216
217
218 Firms should consider the following recommendations when presenting quantitative probability
219 information about their drug’s efficacy and risks.

1. Absolute Frequencies and Percentages

220
221
222
223 Firms presenting quantitative efficacy or risk probabilities in DTC promotional communications
224 should convey the information in terms of absolute frequencies (e.g., 57 out of 100) or
225 percentages (57%). Research suggests that using these formats to express probabilities when
226 communicating health information can improve consumers’ comprehension and ability to recall
227 the information (Lipkus 2007; Zipkin et al. 2014). Additionally, consumers receiving
228 information about a drug’s efficacy and risk rates in terms of absolute frequencies or percentages
229 can more easily process and evaluate the information than when the same information is in a
230 format that requires them to perform a calculation to interpret the probabilities (Lipkus 2007;
231 O’Donoghue et al. 2014b; Sullivan et al. 2015).

232
233 Example 2: A firm is developing a magazine advertisement and includes a presentation
234 showing that in clinical trials, most patients experienced a response after
235 12 weeks of treatment with Drug X.

32 ⁸ Each of the examples in this guidance is intended to stand on its own, and the use of ‘Drug X’ represents a
33 different fictitious drug in each example.

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237 The firm wants to add numeric values to the presentation to help consumers
238 understand this information.

239
240 To communicate this information in a manner that will facilitate consumer
241 comprehension, the firm presents the information as an absolute frequency: *In a*
242 *clinical trial, 78 out of 100 patients experienced a response after 12 weeks of*
243 *treatment with Drug X, compared to 20 out of 100 patients on placebo.*

244
245 Example 3: A firm plans to include quantitative information in a patient mailer for Drug X
246 about the most common adverse reaction reported in its clinical trial that
247 compared Drug X to Drug Y: nausea.

248
249 To allow consumers to easily process this information, the firm presents the
250 information as a percentage: *In a clinical trial, 45% of patients experienced*
251 *nausea during 20 weeks of treatment with Drug X, compared to 18% of patients*
252 *during treatment with Drug Y.*

253 254 2. Relative Frequencies

255
256 Research suggests that consumers do not understand relative frequencies (e.g., 33% reduction in
257 symptoms; 3 times as likely to experience a side effect) in health communications as easily as
258 they understand other formats for presenting probabilities, such as absolute frequencies or
259 percentages (Covey 2007; Fagerlin et al. 2007; Zipkin et al. 2014). Consumers may also find the
260 efficacy or risk probability described as a relative frequency harder to comprehend and more
261 favorable as compared to the absolute frequency, which could lead to consumers' over- or
262 underestimating how well the drug works or the magnitude of the risk associated with the drug
263 (Ancker et al. 2006; Covey 2007; Zipkin et al. 2014).

264
265 If firms choose to present efficacy or risk probabilities as relative frequencies, they should add
266 context to the relative frequency presentation to improve consumers' ability to accurately
267 understand the efficacy or risk information. Specifically, firms should include the corresponding
268 absolute probability measures in presentations of relative frequency measures to provide the
269 information in a way that does not require further calculation about the effect being
270 communicated (Covey 2007; O'Donoghue et al. 2014b; Sullivan et al. 2015). Firms should
271 present the absolute probability measure prominently and in direct conjunction with the relative
272 frequency measure.

273
274 Example 4: A firm is developing a DTC television advertisement for Drug X, which is
275 indicated to reduce the risk of stroke. In a clinical trial, the following absolute
276 risk reductions were observed: 1% of patients treated with Drug X had a stroke,
277 compared to 2% of patients in the control group. This represents a 50% relative
278 reduction in risk of stroke.

279
280 The firm wants to include this information in the DTC television advertisement.

281

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282 To communicate this information in the DTC television advertisement in a
283 manner that will facilitate consumer comprehension, the firm presents the
284 absolute risk percentages in direct conjunction with the 50% relative risk
285 reduction information and with equal prominence: *In a clinical trial, Drug X*
286 *reduced the risk of stroke by 50% (1% of patients treated with Drug X had a*
287 *stroke, compared to 2% of patients in the control group).*

288

289 C. Formatting Quantitative Efficacy or Risk Information

290

291 Firms that provide quantitative efficacy or risk information about their drugs in DTC
292 promotional communications should incorporate the following formatting recommendations:

293

294 • Present the information in the same numerical format throughout a promotional
295 communication (Lipkus 2007; Trevena et al. 2013). For example, firms providing two
296 probabilities about two efficacy outcomes should provide both probabilities as absolute
297 frequencies or provide both probabilities as percentages. Firms should also consistently
298 characterize efficacy or risk information quantitatively throughout a promotional piece,
299 rather than alternating between qualitative descriptors and quantitative information to
300 describe similar information or concepts.

301

302 • Use frequencies with the same denominator when providing more than one absolute
303 frequency and consider using denominators that are multiples of 10 (Fagerlin et al. 2007;
304 Lipkus 2007; Trevena, et al. 2013; Visschers et al. 2009).

305

306 • Express probabilities using whole numbers to the extent that the probabilities in whole
307 numbers accurately reflect the numerical value being described in the promotional piece
308 (Lipkus 2007; Zipkin et al. 2014).⁹ Where a whole number would not be appropriate,
309 firms should express the value as is (e.g., as a decimal) instead of rounding the value up
310 or down to the nearest whole number. For example, firms should not round probabilities
311 less than 1 to the nearest whole number. Similarly, firms should not round probabilities
312 to the nearest whole number when comparing probabilities that are so close in value that
313 the difference between the probabilities would be lost if the values were expressed as a
314 whole number or numbers.

315

316 • Promotional communications should present quantitative probability information about a
317 particular risk in a manner that does not minimize or detract from information about the
318 severity of the risk. Promotional communications should avoid presentations that focus
319 attention on the low probability of a serious risk occurring, that characterize the
320 probability of that risk occurring as insignificant, or that otherwise suggest that the risk is
321 not important based on its probability of occurring.

322

323 Example 5: A firm is developing a consumer brochure for Drug X and is considering whether
324 to describe quantitative information about moderate symptom relief in patients

34 ⁹ For values greater than 1, to express a value to the nearest whole number, the following principles should be
35 followed: For amounts falling exactly halfway between two whole numbers or higher (e.g., 2.5 to 2.99), round up
36 (i.e., 3); for values less than halfway between two whole numbers (e.g., 2.01 to 2.49), round down (i.e., 2).

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325 treated with Drug X and treated with placebo in terms of absolute frequencies (9
326 out of 10 and 3 out of 10, respectively) or as percentages (90% and 30%,
327 respectively).

328
329 Although either probability measure would be appropriate to describe these
330 outcomes, to help consumers process the information, the firm should provide the
331 outcomes for both the treatment and placebo groups in the same format (i.e., both
332 outcomes as absolute frequencies or both outcomes as percentages): *In patients*
333 *treated with Drug X, 9 out of 10 patients experienced moderate symptom relief,*
334 *compared to 3 out of 10 patients who received placebo. Alternatively: In*
335 *patients treated with Drug X, 90% of patients experienced moderate symptom*
336 *relief, compared to 30% of patients who received placebo.*

337
338 Example 6: In a clinical trial for Drug X, 54% of patients treated with Drug X experienced
339 moderate symptom relief and 19% of patients treated with Drug X experienced
340 complete symptom relief, compared to 28% of patients treated with placebo and
341 2% of patients treated with placebo, respectively.

342
343 The firm is developing a patient booklet for Drug X that contains the following
344 information: In a clinical trial, the majority of patients experienced moderate
345 symptom relief after treatment with Drug X, and 19% of patients experienced
346 complete symptom relief. In patients treated with placebo, less than half of
347 patients experienced moderate symptom relief and 2% of patients experienced
348 complete symptom relief.

349
350 To present the information consistently, the firm should include the “*majority of*
351 *patients (54%)*” and “*less than half of patients (28%)*” in the proposed patient
352 booklet. Alternatively, the firm could consistently present only the quantitative
353 information throughout the piece (e.g., “*...54% of patients treated with Drug X*
354 *experienced moderate symptom relief...*,” “*...28% of patients treated with placebo*
355 *experienced moderate symptom relief...*”).

356
357 Example 7: According to the FDA-approved labeling for Drug X, 2% of clinical trial
358 participants on Drug X experienced bleeding that required hospitalization.

359
360 In its promotional communications for Drug X, the firm includes the statement,
361 “In a clinical trial, only 2% of patients experienced bleeding that required
362 hospitalization.”

363
364 By including the qualifier *only* in the description of the percentage of patients
365 who experienced bleeding that required hospitalization, the presentation
366 characterizes the percentage of patients who experienced this risk in a way that
367 could suggest it is not important and may also undermine audience understanding
368 of the serious nature of the risk. *To avoid these possibilities, the firm should*
369 *revise this presentation to remove the qualifier “only.”*

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D. Visual Aids

When DTC promotional communications contain quantitative efficacy or risk information, visual aids such as graphs, tables, and icon arrays are often used to illustrate the information and put the numerical values in context. Visual representations of efficacy and risk in DTC promotional communications improve consumer comprehension of numeric values by illustrating patterns, summarizing the data, and reducing the amount of mental calculations the consumer must perform to extract meaning from the quantitative information (Ancker et al. 2006; Fagerlin et al. 2007; Lipkus 2007). Moreover, visual aids can improve consumers' ability to accurately understand how well a drug works and support decision making (Fagerlin et al. 2007; Garcia-Retamero and Cokely 2013; Sullivan et al. 2016; Zipkin et al. 2014).

Visual aids in DTC promotional communications help consumers comprehend quantitative efficacy and risk information, but all visual aid designs are not equally effective in conveying all types of information (Fagerlin et al. 2007; Sullivan et al. 2016). Therefore, we recommend that firms select the visual aid design that best communicates the quantitative efficacy or risk information being presented. When choosing a visual aid to express quantitative efficacy or risk information about a drug, firms should carefully consider the communication's purpose and objectives (Ancker et al. 2006; Fagerlin et al. 2007). For example, a bar graph is an appropriate format for visually depicting comparisons between probabilities, whereas a line graph is more useful for illustrating trends or changes over time (Ancker et al. 2006; Fagerlin et al. 2007; Lipkus 2007). Additionally, firms should consider the following general recommendations when designing visual aids to illustrate quantitative efficacy or risk information in their DTC promotional communications:

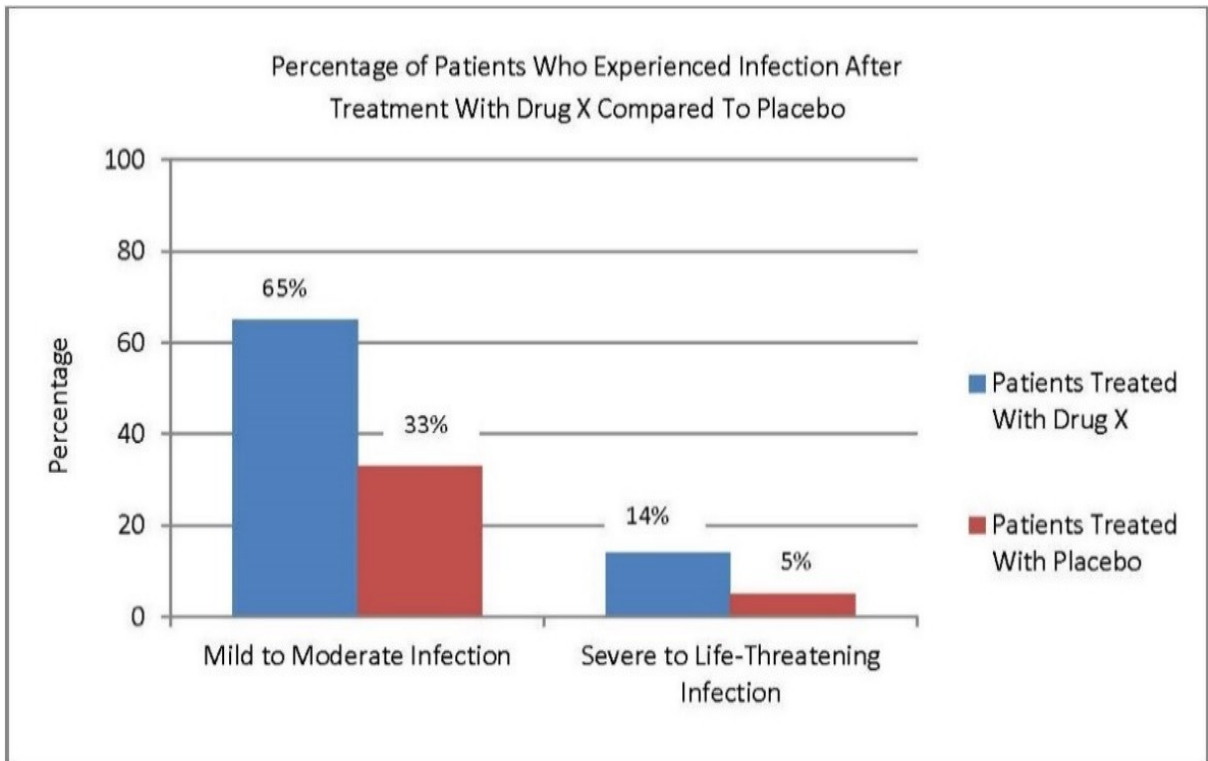
- Explain the purpose of the visual aid clearly and accurately, and define the elements displayed (Garcia-Retamero and Cokely 2013; Lipkus 2007). For example, firms should include a title, header, or caption (written or oral depending on the media) and identify the visual aid's variables, scales, and axes (when applicable).
- Make visual displays of numeric information proportionate to the quantity being described and ensure the scaling of axes is appropriate to accurately represent effect sizes (Ancker et al. 2006; Lipkus 2007). For example, the height of each bar on a vertical bar graph should be proportionate to the numerical value it represents and the scaling of the y-axis should ensure the difference in heights between bars is proportional to the difference in value.
- Include visual representations of both the numerator and denominator of ratios or frequencies (Ancker et al. 2006). For example, an icon array, graph, or other visual aid depicting an absolute frequency should represent the people who experienced the effect (numerator) and the total people studied (denominator). When possible, firms should also consider illustrating the denominator as a multiple of 10 in the display.

Example 8: Drug X is used to treat a serious condition. Infection is a risk associated with the use of Drug X.

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417 The firm intends to include a visual aid on Drug X’s consumer website to
418 communicate information from Drug X’s FDA-approved labeling about the
419 percentage of patients who experienced a mild to moderate infection and those
420 who experienced a severe to life-threatening infection after treatment with Drug X
421 compared to patients treated with placebo.
422

423 *The firm prepares a bar graph to present this information because it facilitates*
424 *the comprehension of visual comparisons between probabilities. As illustrated*
425 *below, the firm includes a title that describes what the bar graph portrays, labels*
426 *the scales and variables, does not truncate the y axis, and ensures that the values*
427 *graphically displayed are proportionate to the quantities being described.*
428



429
430
431

IV. PAPERWORK REDUCTION ACT OF 1995

432 This guidance contains information collection provisions that are subject to review by the Office
433 of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C.
434 3501-3521).
435
436

437
438 The time required to complete this information collection is estimated to average 2 hours per
439 response, including the time to review instructions, search existing data sources, gather the data
440 needed, and complete and review the information collection. Send comments regarding this
441 burden estimate or suggestions for reducing this burden to:

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443 Office of Prescription Drug Promotion, Center for Drug Evaluation and Research, Food
444 and Drug Administration, 10903 New Hampshire Avenue, Bldg. 51, Silver Spring, MD
445 20993-0002.

446

447 This guidance also refers to previously approved FDA collections of information. The
448 collections of information in 21 CFR 202.1 have been approved under OMB control number
449 0910-0686.

450

451 An Agency may not conduct or sponsor, and a person is not required to respond to, a collection
452 of information unless it displays a currently valid OMB control number. The OMB control
453 number for this information collection is 0910-0686 (expires 08/31/2024).

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