

The Value Of Benefit Data In Direct-To-Consumer Drug Ads

Simple tables showing drugs' expected outcomes are understood and valued by consumers.

by **Steven Woloshin, Lisa M. Schwartz, and H. Gilbert Welch**

ABSTRACT: Direct-to-consumer (DTC) pharmaceutical ads typically describe drug benefits in qualitative terms; they rarely provide data on how well the drug works. We describe an evaluation of a “prescription drug benefit box”—data from the main randomized trials on the chances of various outcomes with and without the drug. Most participants rated the information as “very important” or “important”; almost all found the data easy to understand. Perceptions of drug effectiveness were much lower for ads that incorporated the benefit box than for ads that did not. Most people we interviewed want benefit data in drug ads, can understand these data, and are influenced by them.

PROPOONENTS OF DIRECT-TO-CONSUMER (DTC) drug advertising claim that the ads teach consumers about new medicines and treatment options.¹ For ads to serve this educational function, however, physicians and patients need to know to what extent the drug works. This is particularly true for drugs whose effects are not directed at symptoms and thus not directly experienced by patients, such as cholesterol-lowering drugs to reduce the risk of heart disease and platelet inhibitors to reduce the risk of recurrent heart attack or stroke. Because it expands the market for pharmaceuticals so dramatically, the passage of a Medicare drug benefit in November 2003 adds some urgency to the need for more informative DTC drug ads.

In practice, DTC ads provide limited information on how well the drug works. The U.S. Food and Drug Administration (FDA) requires information about potential harms, which appears in fine print on the “brief summary” page.² In contrast, information on drug benefit is not required (the ad must simply note the drug’s indication), and most ads assert that drugs work using vague, qualitative terms (for example, “Zyrtec works,” “lower your number”) rather than presenting actual data.³ Only about a tenth of DTC ads provide data about drug benefit in either the

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ad or the accompanying brief summary.⁴

Ironically, the absence of benefit data may lead some patients to assume that the drug always works; physicians cited exaggerated perception of benefit as the most significant problem these ads create for their practice, according to a recent FDA-sponsored survey.⁵ Nearly one-quarter of Americans believe that only “extremely effective” drugs can be advertised to consumers.⁶ To make drug benefit data readily available, we created a “prescription drug benefit box”—a standardized table with published data on the chances of various outcomes with and without the drug—to supplement the brief summary provided with three current DTC ads. The benefit box was modeled on the FDA’s “Nutrition Facts” box (appearing on food packaging). We then conducted a study to learn whether consumers really understand and value drug benefit data.

Methods

■ **Study advertisements.** We selected three current print DTC drug advertisements that met the following criteria: The advertised drug was for a common medical condition, and the advertisement clearly specified the purpose of the medication in the main part of the ad. We constructed two versions of each ad (for a total of six ad versions): a standard version, which replicated the published ad and brief summary, and a benefit box version, which had the identical ad and a brief summary that included the benefit box (note that all versions of the advertisements are available online).⁷

■ **Standard version.** The standard version of the ad replicated the published ad except for three changes. To avoid preconceived notions about effectiveness from people already taking these medications, we devised alternative names for the drugs and drug companies in the ads and brief summaries using modified pig Latin. To make the standard brief summary version as similar as possible to the benefit box version, we also made the following changes. We slightly rearranged the position of some of the text (we did not alter the text size) to clear an approximately 3.5 inch by 2 inch space for the benefit box. For one ad (pravastatin), we edited the content so that it only focused on consumers who had not had a heart attack. The three drug advertisements were as follows.

Pravastatin. Pravastatin is a cholesterol-lowering agent to reduce heart attack risk, sold under the brand name Pravachol. The Pravachol ad shows a pencil with a list of facts, and the headline reads, “Maybe it’s time to learn the facts. Pravachol is the only cholesterol lowering drug proven to help protect against 1st and 2nd heart attack and stroke.” To focus the ad on primary prevention, we changed the headline to “...proven to help protect against heart attack” (the approved indication for primary prevention) and omitted “1st and 2nd heart attack and stroke” (the approved indication for secondary prevention) from the rest of the ad. In the study advertisement, Pravachol was renamed Avastat.

Rofecoxib. Rofecoxib is a cyclooxygenase-2 (COX-2) inhibitor to reduce arthritis

pain, sold under the brand name Vioxx. The Vioxx ad shows a man digging for clams with his dog at low tide, and the headline reads, “The clams were the only ones that benefited from my arthritis. Sorry guys, I’m back.” In the study advertisement, Vioxx was renamed Ofecox.

Clopidogrel. Clopidogrel is an antiplatelet agent to reduce second heart attacks and strokes, sold under the brand name Plavix. The Plavix ad shows a man standing at the edge of the Grand Canyon, and the headline reads, “You don’t want another heart attack or another stroke to sneak up on you.” In the study advertisement, Plavix was renamed Pridclo.

■ **Benefit box version.** The benefit box version of each ad was identical to the standard version except for the addition of the benefit box to the lower right-hand corner of the brief summary. The benefit box is simply a table presenting the proportion of people experiencing various outcomes with and without the drug.⁸ We expressed numbers as percentages and rounded them to the nearest whole number.⁹ We also included a one-word summary to describe the direction of the effect (for example, “fewer”). For each drug, the efficacy data came from the published article of the randomized trial cited in the FDA drug approval document, which matched the indication and outcome in the advertisement.

Pravastatin. These data came from the only randomized trial of primary prevention for people with high cholesterol cited in the FDA approval document (and the approved label) for pravastatin: the West of Scotland Coronary Prevention Group study.¹⁰ The benefit box presented data on the five-year risk of having a heart attack, dying from a heart attack, and dying for any reason (all-cause mortality) for pravastatin versus placebo (Exhibit 1).

Rofecoxib. These data came from the largest published randomized trial cited in the FDA approval document, which compared Vioxx to ibuprofen for the treatment of osteoarthritis (this was one of the two “pivotal studies” submitted comparing Vioxx against ibuprofen). The benefit box presented data on patients’ rat-

EXHIBIT 1
Benefit Box Used In The Before-After Comparison With Data For A Cholesterol-Lowering Drug

Benefit of AVASTAT (Avaprastatin)

In a study, people with high cholesterol either took AVASTAT or a sugar pill; here are the percentages of people who experienced the following over 5 years

Effect on patient	Given sugar pill	Given AVASTAT	Effect of AVASTAT
Have a heart attack	8%	6%	Fewer
Die from heart attack	2%	1%	Fewer
Die (from anything)	4%	3%	Fewer

SOURCE: Efficacy data are from the West of Scotland Coronary Prevention Group’s randomized trial of pravastatin versus placebo. J. Shepherd et al., “Prevention of Coronary Heart Disease with Pravastatin in Men with Hypercholesterolemia,” *New England Journal of Medicine* 333, no. 20 (1995): 1301–1307.

ing of the medication’s effect on their arthritis symptoms (excellent, good, fair, poor, or no effect) for rofecoxib versus ibuprofen at six weeks (Exhibit 2).¹¹

Clopidogrel. These data came from the only randomized clinical trial cited in the FDA approval document (and approved label) for the secondary prevention of heart attack and stroke: Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events (CAPRIE).¹² The benefit box presented data on the two-year risk of having a stroke or heart attack, dying from a stroke or heart attack, or dying for any reason for clopidogrel versus aspirin (Exhibit 3).

■ **Advertisement evaluation.** Trained field interviewers from the Center for Survey Research at the University of Massachusetts, Boston, were assigned to census blocks in the following towns in the greater Boston area: Andover, North Reading, Newburyport, Fall River, New Bedford, Chelmsford, Lowell, Brookline, Brighton, Cambridge, Belmont (MA); Providence (RI); and Newport (NH). On each block, they knocked on doors and interviewed up to four English-speaking adults who had no obvious cognitive impairment. A total of 203 in-person interview were conducted; participants received \$20 for completing the interview. The interviews took an average of twenty-three minutes. The interview was pretested with six subjects recruited via newspaper ads (these subjects are not included in this study).

■ **Before-after comparisons.** After a training task to familiarize people with the three elements of interest (the ad, the brief summary, and the drug benefit box), each participant was shown the standard version of the first drug advertisement. They were then asked to state how effective they thought the drug was (using a five-point Likert scale from “not effective” to “extremely effective”). Participants were then given the benefit box version of the ad and were again asked to rate drug effectiveness. In addition, participants were asked a question to test their ability to use the table. This procedure was repeated for the second drug.¹³

EXHIBIT 2

Benefit Box Used In The Before-After Comparison With Data For A COX-2 Anti-Inflammatory Drug

Benefit of OFECOX (Ofecoxib)

In a study, people with arthritis either took OFECOX or ibuprofen; here are the percentages of people who said the following after 6 weeks

Patient’s rating of the medication on their arthritis symptoms

	Given ibuprofen	Given OFECOX	Effect of OFECOX
Excellent effect	9%	9%	Same
Good effect	43%	50%	More
Fair, poor, or no effect	48%	41%	Fewer

SOURCE: Efficacy data are from a randomized trial of rofecoxib versus ibuprofen. R. Day et al., “A Randomized Trial of the Efficacy and Tolerability of the COX-2 Inhibitor Rofecoxib vs. Ibuprofen in Patients with Osteoarthritis,” *Archives of Internal Medicine* 160, no. 12 (2000): 1781-1787.

EXHIBIT 3
Benefit Box Used In The Randomized Comparison With Data For An Antiplatelet Drug

Benefit of PRIDCLO (Pricogrel)

In a study, people who have had heart attacks or strokes either took PRIDCLO or aspirin; here are the percentages of people who experienced the following over 2 years

Effect on patient	Given aspirin	Given PRIDCLO	Effect of PRIDCLO
Have stroke or heart attack	6%	5%	Fewer
Die from stroke or heart attack	2%	2%	Same
Die (from anything)	3%	3%	Same

SOURCE: Efficacy data are from the CAPRIE randomized trial of clopidogrel versus aspirin. CAPRIE Steering Committee, "A Randomised, Blinded Trial of Clopidogrel versus Aspirin in Patients at Risk of Ischaemic Events (CAPRIE)," *Lancet* 348, no. 9038 (2000): 1329-1339.

■ **Randomized comparison.** Respondents were subsequently asked a few general questions about the benefit box itself (for example, whether they thought the information was important, should be required, and was easy to understand) and then were randomized. People in the intervention group were shown only the benefit box version of the third ad (clopidogrel); the control group saw only the standard version of the ad.

■ **Analysis.** For ease of presentation, we collapsed the five-level Likert response categories for perceptions of drug effectiveness to three levels (extremely/very effective, somewhat effective, and a little/not at all effective). *P* values for the five-level comparisons were quite similar to those for the three-level comparisons. For the before-after comparisons, we used an extended version of McNemar's test because the data are paired. For the randomized comparisons (where the data are unpaired), we tested differences in proportions using the chi-square test. All reported *p* values are based on two-sided tests. For all questions answered by the full sample (N = 203), the maximum margin of error (that is, the 95 percent confidence interval) was approximately 7 percent. All analyses were done using STATA version 8.

Study Results

The 203 study participants represented a wide range of ages, incomes (37 percent reported less than \$25,000 total household income, while 18 percent reported over \$100,000), and education levels (15 percent reported less than high school education, while 22 percent had done some graduate work) (Exhibit 4).

■ **Desire for benefit data.** Before having heard about the benefit box, 92 percent said that they would require data on both benefits and side effects in drug ads (Exhibit 5). After seeing the benefit box, three-quarters of respondents said that they would "pay a lot of attention" to the benefit box if it were included in drug ads, and 67 percent said that they would trust the information in the box more than information on the main page of the ad itself. Almost all (93 percent) preferred the benefit box version to the standard brief summary, 5 percent had no preference, and only 2

EXHIBIT 4
Characteristics Of The Sample In A Study Of Prescription Drug Advertising, 2003

Characteristic	Percent
Demographic	
Mean age (range)	
30-39	25
40-49	20
50-64	26
65+	29
Sex	
Female	65
Race/ethnicity	
Non-Hispanic white	88
Hispanic white	2
Black	4
Asian	4
Other	2
Education	
Less than high school	15
High school graduate	25
Some college	14
College graduate	25
Some graduate school or degree	22
Total household income	
<\$25,000	37
\$25,000-\$49,999	19
\$50,000-\$99,999	26
\$100,000 or more	18
Medication use	
Do you take any medicine to ^a	
Prevent heart attack or stroke	36
Treat any arthritis/joint pain	34
Attention to drug ads	
Paid attention to any advertisements for prescription drugs in past 3 months	50

SOURCE: Veterans Affairs (VA) Outcomes Group Prescription Drug Benefit Box Evaluation, 2003.

NOTES: N = 203. Percentages may not add to 100 percent because of rounding. Item nonresponse was 0 or 1 for all items except income (item nonresponse = 21).

^a Medicines included over-the-counter (such as aspirin) or prescription medications and nutritional supplements.

percent preferred the standard brief summary.¹⁴

■ **Understanding of benefit box.** After seeing the benefit box, respondents felt that the data in it were easy to understand: They assigned the data a mean rank of 8.5 (median rank 9) on a scale from 0 (extremely hard) to 10 (extremely easy to understand). This rating was supported by the fact that almost every respondent was able to correctly extract the appropriate percentages from the table in two test questions (95 percent and 97 percent responded correctly, respectively). Comprehension was high even among those with the least formal educational attainment: 90 percent and 100 percent of those with less than a high school education answered

EXHIBIT 5
Data Desired In Drug Ads, And Comprehension Of And Reaction To Benefit Box, 2003

Desire for benefit data before seeing benefit box ^a	Percent responding
What information do you think should be required in drug ads to the public?	
There should be data on	
Benefits only	2
Side effects only	2
Both benefits and side effects	92
Neither benefits nor side effects	5
Reactions to benefit box	
In your opinion, how important is it that the information in the benefit box be included in ads for prescription drugs?	
Very important	72
Important	19
A little important	5
Not important	3
If you were reading an ad for a prescription drug that included a benefit box, how much attention would you pay to the information in the box?	
A lot	75
Some	17
A little	5
None at all	3
How would you feel about seeing this ad?	
Strongly prefer ad with benefit box	78
Slightly prefer ad with benefit box	15
No preference	5
Slightly prefer ad without benefit box	1
Strongly prefer ad without benefit box	1
How much do you trust the information in the benefit box compared to the first page of the ad?	
More	67
Same	29
Less	4
Understanding of benefit box	
What percentage of people given AVASTAT had a heart attack?	97 ^b
What percentage of people given OFECOX said that it had an excellent effect on their arthritis symptoms?	95 ^b

SOURCE: Veterans Affairs (VA) Outcomes Group Prescription Drug Benefit Box Evaluation, 2003.

NOTES: N = 203. Percentages may not add to 100 percent because of rounding. Item nonresponse for these items ranged from 0 to 4. On a scale of 0 (extremely hard) to 10 (extremely easy), respondents ranked how easy or hard it was to understand the box at a mean of 8.5 (standard deviation, 2).

^a This was the first question of the interview, asked before participants were told about the study details or benefit box.

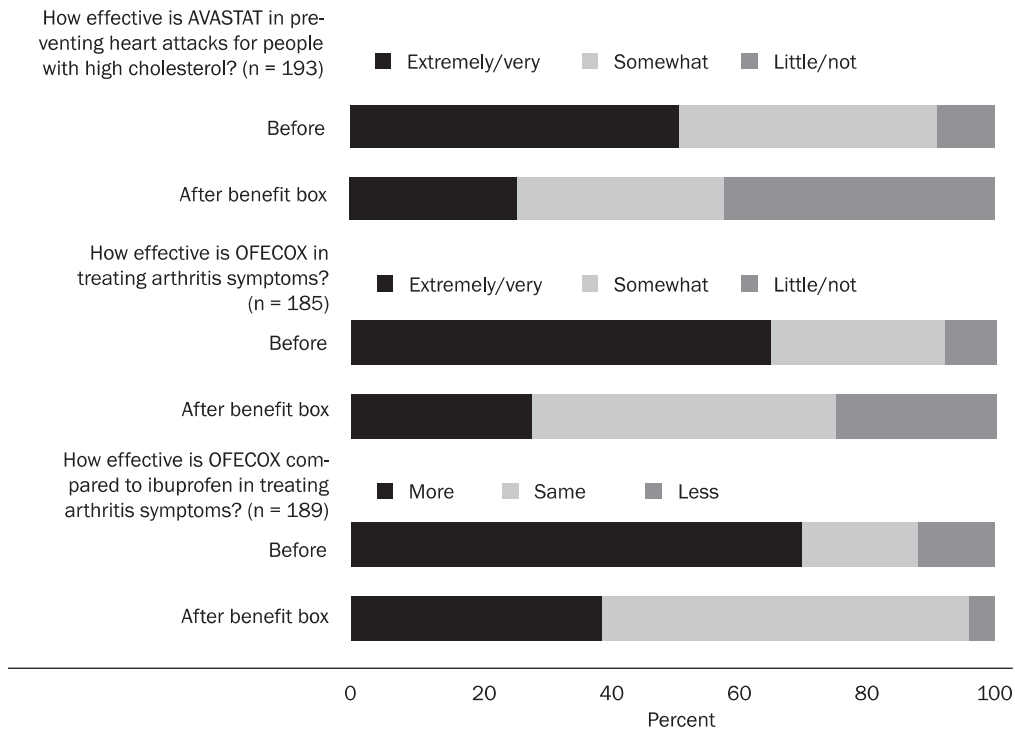
^b Percentage correctly extracting the information from the benefit box.

these two questions correctly.

■ **Perceptions of drug effectiveness.** *Before-after comparisons.* Seeing the standard version of the ad, most respondents rated the drugs as “extremely or very effective”: 51 percent gave this rating to Avastat (15 percent rated it as extremely effective); 65 percent, to Ofecox (17 percent rated it as extremely effective) (Exhibit 6).

EXHIBIT 6

Perceived Effectiveness Of Drugs With Standard Version Of Drug Ad And After Seeing Benefit Box Version Of Drug Ad, 2003



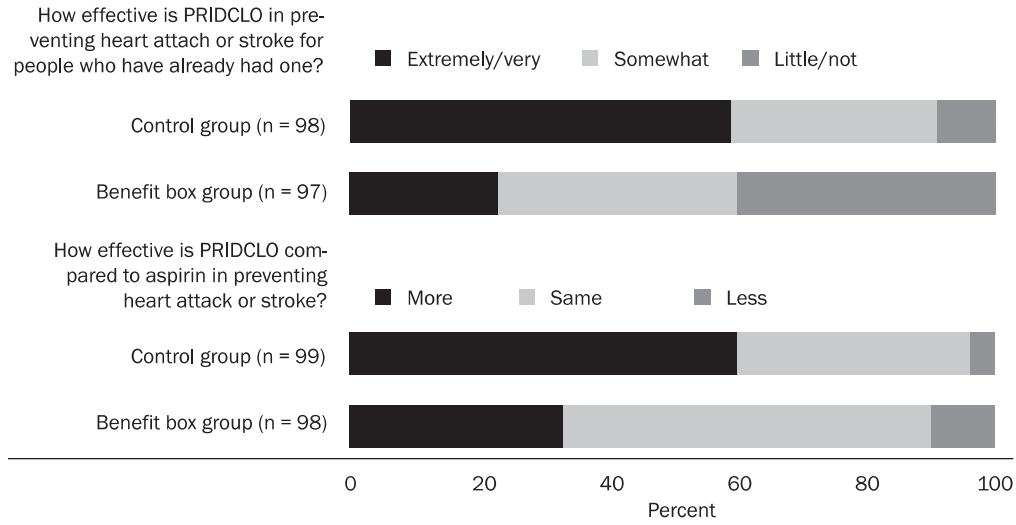
SOURCE: Veterans Affairs (VA) Outcomes Group Prescription Drug Benefit Box Evaluation, 2003.
NOTE: $p < .001$ for McNemar test to compare distributions across response variables for before-after comparisons.

After being presented with quantitative efficacy data from the randomized trial in the benefit box version, the proportion of respondents rating the two drugs as extremely or very effective fell—to 26 percent for Avastat and 28 percent for Ofecox (both $p < .001$). The presence of the benefit box also caused many more respondents to correctly rate the effectiveness of Ofecox as being “about the same” as that of ibuprofen (18 percent with the standard version versus 57 percent with the benefit box version, $p < .001$).

Randomized comparisons. Exhibit 7 shows the results for the randomized portion of the study, in which participants received only one of the two ad versions for the third drug, Pridclo. Again we found that the presence of the benefit box was associated with much lower perceived effectiveness: The proportion rating Pridclo as “extremely” or “very” effective was 59 percent in the standard version group versus 23 percent in the benefit box version group ($p < .001$). The presence of the benefit box also caused many more respondents to rate the effectiveness of Pridclo as being about the same as that of aspirin (36 percent with the standard version versus 57 percent with the benefit box version, $p = .001$).

EXHIBIT 7

Perceived Effectiveness Of Drugs For People Randomized To The Standard Version Of The Drug 3 Ad (n = 99) Or To The Benefit Box Version Of The Drug 3 Ad (n = 98), 2003



SOURCE: Veterans Affairs (VA) Outcomes Group Prescription Drug Benefit Box Evaluation, 2003.
NOTE: $p \leq .001$ for chi-square tests of differences in distributions across response variables for control group/benefit box group comparisons.

Interpretation And Limitations

We found strong support for including drug benefit data in DTC ads; almost all respondents thought that such data in ads should be required. Almost all respondents also liked the benefit box as a vehicle for communicating these data, rating it as easy to understand and saying that they would pay attention to it. And when given a choice, more than 90 percent preferred an ad that included the box to the standard version without it. Finally, for each ad tested, perceptions of drugs’ effectiveness dropped after respondents saw the benefit box.

Our findings should be interpreted in light of several limitations. First, it is important to acknowledge that our findings are based on an experiment—although 92 percent said that they would pay some or a lot of attention to a benefit box, in real life people might not. Second, both the ads and the study subjects represent convenience samples. The ads were the first ones we found (flipping through current magazines in our local general store) that met our inclusion criteria; subjects consisted of the people who happened to be home and who agreed to participate when an interviewer knocked on their door. Consequently, our results might differ with different ads or different subjects (or even in different geographic locations). However, given the magnitude of our findings and the sociodemographic diversity of our non-self-selected participants, only an extraordinarily powerful confounder could alter our qualitative message.

The impact of the benefit box on perceptions of drug effectiveness raises some

“To really judge how well an advertised drug works, people need some sense of the magnitude of the benefit of typical drugs.”

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legitimate concerns. Our participants were very optimistic about the effectiveness of each study drug; in each case, these perceptions dropped after seeing the actual data. The effect, however, was similar for all drugs. This is a matter of concern, since one of the drugs, Avastat, showed a reduction of overall mortality over five years from 4 percent to 3 percent.¹⁵ We suspect that many respondents did not appreciate the real magnitude of this effect: Few drugs now being manufactured can match this reduction in all-cause mortality among relatively healthy outpatients. But to really judge how well an advertised drug works, people need context—that is, some sense of the magnitude of the benefit of typical drugs. Undoubtedly, most people lack such knowledge. This probably explains why our respondents were less enthusiastic when they saw the actual data for each medication. We believe that reactions to drug benefit data will change as people have more exposure to them; that is, consumers will be better able to discriminate among drugs as they become better calibrated to effect sizes and the importance of different outcome measures.

Policy Implications

DTC drug advertising has been controversial since its inception, with proponents and opponents debating the educational value of the ads and their impact on the physician-patient relationship. Most troubling is the potential for advertising to stimulate inappropriate demand for drugs. The new Medicare prescription drug benefit can only exacerbate the problem. While it laudably provides millions of Americans with improved access to pharmaceuticals, it also has a less desirable effect: It means that millions more consumers may be stimulated by direct marketing to demand drugs inappropriately.

One way to avoid inappropriate demand for advertised medications is to ban DTC ads altogether, a position the European Union has taken for years and recently reaffirmed.¹⁶ European consumer groups argued that the educational material on drugs should “help establish informed choice for patients instead of just more brand awareness” and that this educational function could be fulfilled only by independent authorities, not by the pharmaceutical companies’ ads.¹⁷ Recently, the Ministry of Health in New Zealand—the only country besides the United States where DTC ads are legal—reconsidered its position on them and is pursuing a ban.¹⁸

Another approach is to regulate the content of DTC ads to improve their educational content. The systematic provision of drug benefit data would educate consumers and promote informed decision making by providing easy access to scientific data on drug benefit (drug versus placebo or an appropriate alternative

intervention) whenever a drug advertisement appears. A major challenge to moving forward will be creating practical and valid guidelines to decide which data should be provided—specifically, which outcome measures would be required and which study (or studies) should the data come from. When there is only one main trial supporting a drug’s efficacy for a given indication, study selection will not be an issue. In some cases, generating good benefit data will require a sizable effort to pool data and conduct meta-analyses. The FDA could mandate how such studies should be done or even designate an independent entity to conduct them (perhaps paid for by the drug companies).

To improve the communication of health information to consumers, the FDA recently released draft guidance to pharmaceutical manufacturers with suggestions on how to improve the brief summary in print DTC ads.¹⁹ The guidance, based on research by the FDA and independent investigators and on consumers’ participation at a public FDA meeting in September 2003, is intended to maximize the usefulness of information in DTC ads to consumers and to help inform doctor-patient discussions about “the key risks and benefits of a product.”²⁰ Unfortunately, the draft guidance contains no provisions for the communication of drug benefit data.

Based on our findings, we suggest that the FDA mandate benefit data in the ads. Our study shows that people want such data and have little trouble extracting it from tables as implemented in the benefit box. Presenting benefit and harm data together (in the same tabular format) would make it easy to put data on side effects into context (that is, is this benefit worth the chance of these side effects?) and would promote meaningful patient-physician discussion by giving physicians access to data that they often lack. Requiring drug benefit data in DTC ads is an important step in educating the public about prescription drugs and promoting informed decision making.

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NOTES

1. M. Rosenthal et al., "Promotion of Prescription Drugs to Consumers," *New England Journal of Medicine* 346, no. 7 (2002): 498–505; and L. Fintor, "Direct-to-Consumer Marketing: How Has It Fared?" *Journal of the National Cancer Institute* 94, no. 5 (2002): 329–331.
2. The brief summary includes a list of all harms noted in the drug package insert and sometimes includes a table with data on the frequency of side effects. The brief summary is typically an excerpt from the *Physician's Desk Reference* (PDR). The relevant regulations are found in "Prescription Drug Advertisements," 21 CFR, Part 202.1 (Washington: U.S. Government Printing Office, 2003).
3. *Ibid*; S. Woloshin et al., "Direct to Consumer Drug Advertisements: What Are Americans Being Sold?" *Lancet* 358, no. 9288 (2001): 1141–1146; and R. Bell, M. Wilkes, and R. Kravitz, "The Educational Value of Consumer-Targeted Prescription Drug Print Advertising," *Journal of Family Practice* 49, no. 12 (2000): 1092–1098.
4. Bell et al., "The Educational Value."
5. K.J. Aikin, *Direct-to-Consumer Advertising of Prescription Drugs: Physician Survey Preliminary Results*, 13 January 2003, www.fda.gov/cder/ddmac/globalsummit2003/index.htm (28 January 2004).
6. R. Bell, R. Kravitz, and M. Wilkes, "Direct-to-Consumer Prescription Drug Advertising and the Public," *Journal of General Internal Medicine* 14, no. 11 (1999): 651–657.
7. See content.healthaffairs.org/cgi/content/full/hlthaff.w4.234v1.DC3.
8. The exhibits in this paper do not follow the benefit boxes' formatting exactly as it was presented to study participants but merely provide the information in the boxes. Each ad, the standard brief summary, and the brief summary with the benefit box are available on the *Health Affairs* Web site, as above.
9. We presented data using absolute rates of outcomes since we have found in prior work that this format is the best understood. See L.M. Schwartz et al., "The Role of Numeracy in Understanding the Benefit of Screening Mammography," *Annals of Internal Medicine* 127, no. 11 (1997): 966–972.
10. J. Shepherd et al., "Prevention of Coronary Heart Disease with Pravastatin in Men with Hypercholesterolemia," *New England Journal of Medicine* 333, no. 20 (1995): 1301–1307.
11. R. Day et al., "A Randomized Trial of the Efficacy and Tolerability of the COX-2 Inhibitor Rofecoxib vs. Ibuprofen in Patients with Osteoarthritis," *Archives of Internal Medicine* 160, no. 12 (2000): 1781–1787. Note that this article only presented mean differences in the five-level Likert scale between entry and six-week follow-up (for example, rofecoxib 2.4 levels lower versus ibuprofen 2.3 levels lower). Because we thought that the actual distribution of responses by treatment group would be more easily understood by readers, we obtained these data from the study authors and presented three categories of responses (percentage reporting excellent effect; percentage good effect; and percentage fair, poor, or no effect) in the benefit box.
12. CAPRIE Steering Committee, "A Randomised, Blinded Trial of Clopidogrel versus Aspirin in Patients at Risk of Ischaemic Events (CAPRIE)," *Lancet* 348, no. 9038 (2000): 1329–1339.
13. Because the drugs are so different in terms of indication and efficacy, we randomly assigned participants to see the ads in different orders (that is, pravastatin ads then rofecoxib ads, or rofecoxib ads then pravastatin ads). Although we were concerned that the order of viewing might affect perceptions of effectiveness, it did not, so we report pooled data here.
14. Preference for the benefit box version was the same in both arms of the randomized comparison: 94 percent (standard ad group) versus 91 percent (benefit box group) preferred the benefit box version, $p = .56$.
15. Shepherd et al., "Prevention of Coronary Heart Disease."
16. R. Watson, "EU Health Ministers Reject Proposal for Limited Direct to Consumer Advertising," *British Medical Journal* 326, no. 7402 (2003): 1284.
17. *Ibid*.
18. B. Burton, "New Zealand Moves to Ban Direct Advertising of Drugs," *British Medical Journal* 328, no. 7431 (2004): 68.
19. U.S. Food and Drug Administration, "New FDA Draft Guidances Aim to Improve Health Information (P04-12)," Press Release, 4 February 2004, www.fda.gov/bbs/topics/NEWS/2004/NEW01016.html (17 March 2004).
20. *Ibid*; and FDA, "Direct-to-Consumer Promotion: Public meeting, September 22 and 23, 2003," www.fda.gov/cder/ddmac/DTCmeeting2003.html (28 January 2004). Preliminary results of our evaluation were presented at this meeting.