Communicating Composite Scores in Direct-to-Consumer (DTC) Prescription Drug Advertising

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

Regulatory Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes the Food and Drug Administration (FDA) to conduct research relating to health information. Section 903(b)(2)(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(c)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

Composite Scores

To market their products, pharmaceutical companies must demonstrate to the Food and Drug Administration (FDA) the efficacy and safety of their drugs, typically through well-controlled clinical trials.[1] In some cases, drug efficacy can be measured by a single endpoint, such as high blood pressure.[2] Often, however, efficacy is measured by multiple endpoints that are sometimes combined into an overall score called a composite score.[3] For example, nasal allergy

[1] Lipsky, M.S., & Sharp, L.K. (2001). From idea to market: The drug approval process. *Journal of the American Board of Family Practitioners, 14(5)*, 362-367; Food, Drug, and Cosmetic Act, Sec. 505, 21 U.S.C. § 355. (2008). Retrieved from http://www.fda.gov/regulatoryinformation/legislation/FederalFoodDrugand CosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108125.htm

[2] Rutan, G. H., McDonald, R. H., & Kuller, L. H. (1989). A historical perspective of elevated systolic vs. diastolic blood pressure from an epidemiological and clinical trial viewpoint. *Journal of Clinical Epidemiology, 42*(7), 663–673.

[3] Agency for Healthcare Research and Quality (AHRQ). (2012). *Combining measures into composite or summary scores.* Retrieved from https://www.talkingquality.ahrq.gov/content/create/scores/combinemeasures.aspx; American Medical Association. (2010). *Measures Development, Methodology, And Oversight Advisory Committee: Recommendations to PCPI work groups on composite measures*. Retrieved from http://www.ama-assn.org/resources/doc/cqi/composite-measures-framework.pdf

relief is measured by examining individual symptoms such as runny nose, congestion, nasal itchiness, and sneezing. Each symptom is measured on its own. An overall score is computed from the individual symptom measurements; if a drug has a significantly better overall score than the comparison group (e.g., placebo), it can be marketed for the relief of allergy symptoms. However, although a drug may have a significantly better score overall, it may not have a significantly better score on a particular aspect (e.g., runny nose). Scientists and medical professionals have had training to understand the difference between composite score endpoints and single endpoints, but members of the general public may not understand the difference.

Given the frequency of direct-to-consumer (DTC) advertising, it is important to determine whether consumers understand composite scores as they are currently communicated and how best to communicate such scores to lay audiences in general. Because most DTC prescription drug ads do not explicitly state that they used composite scores to demonstrate efficacy or they provide little explanation of how these scores are calculated, it is also important to investigate whether consumers understand how composite scores are used for measuring drug efficacy.

Prior research on composite scores is scant. Therefore, in September 2011, FDA conducted a focus group study (OMB Control No. 0910-0677) to better understand how consumers understand the concept of composite scores. Prior to the focus group, few participants had heard the term “composite score,” none were aware of how the scores might be used in clinical trials, and most participants had difficulty correctly interpreting efficacy information that was based on composite scores. Once the moderator explained composite scores to participants, some reassessed their opinion of the advertised drug’s effectiveness and said they thought that the information on effectiveness was “much less convincing,” in many cases because it was unclear whether the drug would work for a particular symptom. As a result, some participants said they would want a drug

ad to include more detailed information on the effectiveness of the drug on each component of the composite score. However, others felt that the ads already provided enough information on effectiveness and that adding more statistical details would make the ads more complicated, thus decreasing the likelihood that consumers would read them.

The focus group findings suggest that research is required to examine how the inclusion of increasingly detailed information affects understanding of composite scores and influences perceptions of efficacy. This is especially important given the many marketed prescription drugs that are based on composite scores.

We are aware of no quantitative research on best practices for communicating composite score information to consumers. One related area of research, communicating health-related information to consumers, offers two practical recommendations that are particularly relevant to communicating composite scores in DTC advertisements. First, because less-numerate and less-literate consumers may not understand the information as well, examining differences in comprehension of composite scores by numeracy- and literacy-relevant demographic characteristics such as education level and age is important.[4] Second, although the literature tends to suggest limiting the amount of information presented in advertisements,[5] examining the

[4] Fagerlin, A., & Peters, E. (2011). Quantitative information. In B. Fishoff, N. T. Brewer, & J. S. Downs (Eds.), *Communicating risks and benefits: An evidence-based user guide.* Food and Drug Administration, U.S. Department of Health and Human Services. Retrieved from http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm268078.htm; Peters, E., Vastfijall, D., Slovic, P., Mertz, C. K., Mazzzocco, K., & Dickert, S. (2006). Numeracy and decision making. *Psychological Science, 17*(5), 407–413.

[5] Peters, E., Vastfijall, D., Slovic, P., Mertz, C. K., Mazzzocco, K., & Dickert, S. (2006). Numeracy and decision making. *Psychological Science, 17*(5), 407–413; Gurmankin, A. D., Baron, J., & Armstrong, K. (2004). The effects of numerical statements of risk on trust and comfort with hypothetical physician risk communication. *Medical Decision Making, 24*(3), 265–271; Edwards, A., Thomas, R., Williams, R., Ellner, A. L., Brown, P. & Elwyn, G. (2006). Presenting risk information to people with diabetes: Evaluating effects and preferences for different formats by a web-based randomized controlled trial. *Patient Education Counseling, 63,* 336–349.

amount of detail that best facilitates comprehension of composite scores is warranted.

2. Purpose and Use of the Information Collection

Given the lack of research on consumer understanding of composite scores and how to best present this information in DTC advertisements, the main goal of the current research is to evaluate how consumers interpret and respond to DTC prescription drug advertising that includes benefit information based on composite scores. Specifically, this research will explore:

1. whether consumers are aware of how efficacy is measured for specific drugs;
2. how well consumers comprehend the concept of composite scores;
3. whether exposure to DTC advertisements with composite scores influences consumers' perceptions of a drug's efficacy and risk; and
4. different methods for presenting composite scores in DTC ads to maximize consumer comprehension and informed decision-making.

Data will be collected by an independent contractor and shared with FDA electronically. No personally identifiable information will be sent to FDA. All information that can identify individual respondents will be maintained by the independent contractor in a form that is separate from the data provided to FDA. The data shared with FDA will be used to answer the research questions. The proposed data collection should have no impact on privacy.[6]

3. Use of Improved Information Technology and Burden Reduction

Automated information technology will be used in the collection of information for this study. The contracted research firm will collect data through Internet administration. One hundred percent (100%) of participants will self-administer the Internet survey via a computer, which will record responses and provide appropriate probes when needed. In addition to its use in data

[6] This paragraph satisfies sections D.b.2 and D.b.3 of the OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.

collection, automated technology will be used in data reduction and analysis. Burden will be reduced by recording data on a one-time basis for each respondent and by keeping surveys to less than 20 minutes.

4. Efforts to Identify Duplication and Use of Similar Information

We are aware of no published studies examining the communication of composite score information to consumers. Past research has examined the communication of other various quantitative concepts (see footnote 5), but not composite scores. Because this is such a critical piece of the scientific puzzle behind the determination of drug efficacy, this is a valuable concept to examine.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

The proposed data collection is one-time only. There are no plans for successive data collections.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This collection of information fully complies with 5 CFR 1320.5. There are no special circumstances.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of August 23, 2012 (77 FR 51027). FDA received four public submissions. One submission discussed bird flu and another submission discussed graphic warnings on cigarette packages. Both of these comments are outside the scope of the present

project. In the following section, we outline the observations and suggestions raised in the other two submissions and provide our responses:

(Comment 1) One comment mentioned the respondents who were identified as screeners, wondering who these individuals were and what their roles will be.

(Response) These individuals are members of the internet panel who are screened for participation. They originate from the same source as participants who complete the whole survey but either do not meet the criteria in the screener or choose not to participate in the study.

(Comment 2) One comment mentioned that ensuring adequate power is an important consideration.

(Response) We agree that power analysis is critical to ensure that participants' time is used wisely and that the research meets high standards of rigor. We have included power analyses in Part B.

(Comment 3) One comment questioned whether the understanding of composite scores is more applicable to print or video ads and suggested that we ensure we are delivering the sample ad in the medium consumers will be most likely to use.

(Response) Because this is the first study to our knowledge that specifically examines the understanding of composite scores, we have chosen to examine them in the context of magazine ads. Magazine ads for prescription drugs are common. Pending the results of the current research, we may examine the issues in video format.

(Comment 4) One comment mentioned that we have not addressed the issue of non-response.

(Response) We will perform a non-response analysis to determine whether respondents were biased in the direction of any demographic characteristics. This non-response analysis and methods to deal with non-response are described in part B.3.

(Comment 5) The comment suggested that because FDA conducted focus groups on the understanding of composite scores, that there is no need to conduct quantitative research.

(Response) FDA respectfully disagrees. Focus groups are small, qualitative interviews among a group of individuals. Focus groups are composed of individuals who are not representative of any population and the number of people queried is too small to draw firm conclusions. The value of focus group research is the exploration of topics for potential future study; to determine what language people use to discuss topics; and to strengthen the details of future quantitative research that may be conducted by FDA. What we learned from the focus groups on composite scores is that there is a need for research to determine how widespread misconceptions are and whether there are methods available to remedy them. To gain confidence in our qualitative findings, a quantitative approach and measures are necessary.

(Comment 6) This comment suggested that because a health care professional is involved in the prescribing of prescription drugs, the misunderstanding of composite scores is mitigated.

(Response) We agree that the health care professional is the prescriber and that the consumer or patient has a layer of protection before consuming prescription drugs. However, direct-to-consumer advertising is directed at consumers, often reaching them before they talk to their health care professionals—in fact, driving consumers to their health care professionals is a primary goal of DTC. If sponsors choose to communicate with consumers in such a manner, then it makes sense to examine the understandability of their messages.

(Comment 7) This comment stated that because the meaning of composite scores in serious medical conditions may differ from that in allergy situations, FDA should take care in not generalizing beyond what the results suggest in the nasal allergy category.

(Response) We agree. Because we have designed only two studies to examine this issue, we have by necessity chosen one medical condition for each. We will be cautious in applying the findings of our research.

(Comment 8) This comment suggested leveraging the brief summary to improve consumer understanding of composite scores. They suggest including a signal, such as an asterisk, to information in the brief summary about composite scores. They also suggest that the brief summary draft guidance could include language about what the proper explanation of composite scores could be.

(Response) This comment appears to address the draft guidance "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements," and is thus beyond the scope of this project. We encourage the commenter to consider submitting comments to the docket for that guidance, Docket No. 2004D-0042. Comments can be made to any guidance at any time.

(Comment 9) This comment requests that FDA publish a strategic plan that clearly shows which studies are independent and which are connected to each other. This comment also suggests that FDA publish in a timely manner the results of studies posted on the OPDP webpage.

(Response) We agree that timely results should be made available to the public. In the last few years, we have had an increase in the number of research studies and they are all in various states of development. We will publicize them as results become available. We agree the webpage should be updated and are constantly working to make that happen. Please note that this

study is the first to explore composite scores and does not build on any prior research from our office.

(Comment 10) This comment suggests that an assessment of drug effectiveness and risk recall is outside the scope of the stated interest in the study and that information on this study is being collected elsewhere.

(Response) Assessment of effectiveness and risk information are within the scope of our stated interests in composite scores. Anything that is included in a DTC ad has the potential to influence the balance of risks and benefits that must be considered when a consumer makes the decision to speak with their health care professional about a prescription drug. Perceptions of effectiveness are central to issues of understanding composite scores because inappropriate presentations of composite scores could overstate the efficacy of the drug. FDA is always concerned about the communication of risks in DTC promotion. Therefore, it is important to understand if variations in the presentation of composite scores influences the understanding of risks as well. Nonetheless, we are not collecting information on how composite scores may affect risk and benefit accuracy in other studies.

(Comment 11) This comment requests that the results of this study, which address print ads, not be broadly applied to other forms of advertising such as websites, smart phones, and social media.

(Response) We have chosen to investigate the concept of composite scores in a print medium. The concepts we are exploring in this research apply to any similar medium, including static elements of websites.

External Reviewers

In addition to inviting public comment, OPDP sent materials to three individuals for external peer review. The following individuals provided comments:

Hae-Kyong Bang
Associate Professor, Marketing & Business Law
Bartley Hall Room 2065
Villanova University School of Business
800 Lancaster Avenue
Villanova, PA

Joel Davis, Ph.D.
Center for Integrated Marketing Communications
San Diego State University School of Business
San Diego, CA

Mary Ebeling, Ph.D.
Associate Professor of Sociology
Drexel University
Culture and Communication
3141 Chestnut Street
Philadelphia, PA

9. Explanation of Any Payment or Gift to Respondents

Internet panel participants receive points for completing a survey. One thousand base points (approximately monetary equivalence of $1) will be awarded. Members are allowed to use their points to exchange for vouchers and gifts from a partner network. Internet panel participants are enrolled into a points program that is analogous to a 'frequent flyer' card: respondents are credited with sweepstakes entries or bonus points in proportion to their regular participation in surveys. Traditionally, panelists earn sweepstakes entries on some surveys (including surveys more than 20 minutes in length) and bonus points for surveys that are longer or require special tasks by the panel member. Panelists may elect to redeem their points for checks (1,000 points = $1) or raffle entries as they accrue them.

10. Assurance of Confidentiality Provided to Respondents

No personally identifiable information will be sent to FDA. All information that can identify individual respondents will be maintained by the independent contractor in a form that is separate from the data provided to FDA. The information will be kept in a secured fashion that will not permit unauthorized access. The privacy of the information submitted is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)) and by part 20 of the Agency's regulations (21 CFR part 20.63).[7] These methods will all be approved by FDA's Institutional Review Board (Research Involving Human Subjects Committee (RIHSC)) prior to collecting any information.

All respondents will be provided an assurance of privacy to the extent allowable by law. The Internet panel includes a panel privacy policy that is easily accessible from any page on the site. A link to the privacy policy will be included on all survey invitations. The panel complies with established industry guidelines and states that members' personally identifiable information will never be rented, sold, or revealed to third parties except in cases where required by law. These standards and codes of conduct comply with those set forth by the American Marketing Association, the Council of American Survey Research Organizations, and others. In addition, a consent form will be displayed before participants begin the survey (Appendix D). The consent form states that participation is voluntary.[8]

All electronic data will be maintained in a manner consistent with the Department of Health and Human Services' ADP Systems Security Policy as described in the DHHS ADP

---

[7] This section states: "(a) The names or other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted before the record is made available for public disclosure. (b) The names and other information which would identify patients or research subjects should be deleted from any record before it is submitted to the Food and Drug Administration. If the Food and Drug Administration subsequently needs the names of such individuals, a separate request will be made."

This satisfies section D.b.4.1 and D.b.4.2 of the OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.

[8] This satisfies section D.b.4.1 and D.b.4.2 of the OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.

Systems Manual, Part 6, chapters 6-30 and 6-35.[9] All data will also be maintained consistent with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA-Regulated Products).[10]

11. Justification for Sensitive Questions

This data collection will not include sensitive questions. The complete list of questions is available in Appendix B.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The total annual estimated burden imposed by this one-time collection of information is 1,321 hours.

Table 2.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Study 1					
Informed Consent	1,800	1	1,800	0.03	54
Pretest	200	1	200	0.30	60
Main Survey	1,600	1	1,600	0.30	480
Study 2					
Informed Consent	2,202	1	2,202	0.03	66
Pretest	462	1	462	0.30	139
Main Study	1,740	1	1,740	0.30	522
Total	8,004				1,321

[9] This satisfies section D.b.4.3 of the OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.
[10] This satisfies section D.b.4.4 of the OMB Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.

[1] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

These estimates are based on FDA's and the contractor's experience with previous consumer studies.

.

12.b. Annualized Cost Burden Estimate

Table 3. --Estimated Annualized Burden Costs			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General public	1,321	$19.30[1]	$25,495
Total			$25,495

[1]Based on the fourth quarter 2012 median weekly income of $772 for both sexes, as reported by the Bureau of Labor Statistics, http://www.bls.gov/news.release/wkyeng.t01.htm

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no costs to respondents, there are no record keepers, and no Capital and Operating and Maintenance costs

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for the collection of data is $1,068,245 ($356,082 per year for three years). This includes costs paid to the contractor to create measurement instruments, program the study, draw the sample, collect the data, and create a database of the results ($988,245). The task order was awarded as a result of competition. Specific cost information other than the award amount is proprietary to the contractor and is not

public information. The cost also includes FDA staff time to design and manage the study, analyze the results, and draft a report ($80,000; 7.5 hours per week for 3 years).

15. Explanation for Programs Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Conventional statistical techniques for survey data, including descriptive statistics such as means, proportions, and percentages, will be used to describe the data in the first part of the study. In addition, we will utilize repeated measures analysis of variance to examine changes in the subset of the survey items that will be administered both prior to and following a brief explanation of what composite scores are (e.g., perceived efficacy, perceived risk, attitudes toward the brand). Additionally, analysis of variance and regression models will be used to analyze comparisons among demographic groups. (See Part B for detailed information on the design, hypotheses, and analysis plan.) Analysis of variance and regression models will be used to analyze the differences among conditions in the second part of the study. The Agency anticipates disseminating the results of the study after final analyses of the data are completed, reviewed, and cleared. The exact timing and nature of any such dissemination has not been determined but may include presentations at trade and academic conferences, publications, articles, and Internet postings.

Project Timetable:

Task	Estimated Completion Date
External Peer Review	November 2012
RIHSC Review	April 2013
30-day FR notice publication	May 2013
OMB Review of PRA package	September 2013

Data Collection	January 2014
Receipt of Data and Methods Report from Contractor	March 2014
Data Analysis	April 2014
Draft Report	May 2014
Internal Review of Draft Report	September 2014
Revisions	October 2014
Final Report	November 2014

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.