Experimental Study of Comparative Direct-to-Consumer (DTC) Advertising

0910-Number

SUPPORTING STATEMENT A

Submitted by

Division of Drug Marketing, Advertising, and Communications
Center for Drug Evaluation and Research

Food and Drug Administration

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A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

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(b)(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.

Regulations specify that sponsors cannot make comparative efficacy claims in advertising for prescription drugs without substantial evidence, most often in the form of well-controlled clinical trials, to support such claims (21 U.S.C. 202.1(e)(6)(ii); 21 U.S.C. 314.126). FDA has permitted some comparisons based on labeled attributes, such as indication, dosing, and mechanism of action. When substantial evidence does not yet exist, sponsors have used communication techniques that invite implicit comparisons, such as making indirect comparisons, using comparative visuals, and using vaguer language. This study is designed to apply the existing comparative advertising literature to DTC advertising, where little research has been conducted to date.

Moreover, as part of the American Recovery and Reinvestment Act of 2009 (Recovery Act), the Agency for Healthcare Research and Quality (AHRQ) is in the process of securing a large compendium of information on the comparative effectiveness of medical treatments in 14 priority medical conditions, including arthritis, cancer, dementia, depression, diabetes, and substance abuse.[1] As part of this process, they will fund a set of CHOICE (Clinical and Health Outcomes Initiative in Comparative Effectiveness) studies designed to explore comparative effectiveness. When this large project is completed, FDA will have additional information to

[1] http://www.ahrq.gov/fund/cerfactsheets/. Last accessed May 23, 2011.

consider when regulating DTC advertising. It is possible that more DTC advertising will be comparative in nature. In preparation for this change, FDA is embarking on the proposed research to ensure that it has adequate information to assess to what extent comparative DTC ads provide truthful and nonmisleading information to consumers.

Comparative Advertising

Comparative advertisements typically compare two or more named or recognizably presented brands of the same product category, although some comparative advertisements implicitly compare a product to other brands by making superiority statements (e.g., "Only Brand A can be cooked in five minutes or less."). These ads are frequently used for commercial products, such as electronics, food products, and automobiles.

Marketing and advertising studies have investigated the influence of comparative ads, particularly in contrast to noncomparative ads.[2] Research specifically investigating the effects of comparative advertising on consumer attitudes—including attitudes toward the ad, the brand, and product use—has produced mixed results.[3] The research findings on the superiority of comparative versus noncomparative ads on purchase intentions, however, have been more conclusive. Relative to noncomparative ads, comparative ads were shown to result in greater purchase intentions.[4] Finally, other evidence suggests that there may be more potential for

[2] Ang, S. H., & Leong, S. B. (1994). Comparative advertising: superiority despite interference? *Asia Pacific Journal of Management, 11*(1), 33–46; Demirdjian, Z. S. (1983). Sales effectiveness of comparative advertising: An experimental field investigation. *Journal of Consumer Research, 10*, 362–364; Grewal, D., Kavanoor, S., Fern, E. F., Costley, C., & Barnes, J. (1997). Comparative versus noncomparative advertising: a meta-analysis. *Journal of Marketing, 61*(4), 1–15; Priester, J. R., Godek, J., Nayakankuppum, D. J., & Park, K. (2004). Brand congruity and comparative advertising: When and why comparative advertisements lead to greater elaboration. *Journal of Consumer Psychology, 14*(1/2), 115–123.

[3] See, for example, Grewal, D., Kavanoor, S., Fern, E. F., Costley, C., & Barnes, J. (1997). Comparative versus noncomparative advertising: a meta-analysis. *Journal of Marketing, 61*(4), 1–15; Rogers, J.C., & Williams, T.G. (1989). Comparative advertising effectiveness: Practitioners' perceptions versus academic research findings. *Journal of Advertising Research, 29(5)*, 22-37.

[4] Ang, S. H., & Leong, S. B. (1994). Comparative advertising: superiority despite interference? *Asia Pacific Journal of Management, 11*(1), 33–46; Demirdjian, Z. S. (1983). Sales effectiveness of comparative advertising: An experimental field investigation. *Journal of Consumer Research, 10*, 362–364; Grewal, D., Kavanoor, S., Fern, E. F., Costley, C., & Barnes, J. (1997). Comparative versus noncomparative advertising: a meta-analysis. *Journal of*

consumers to confuse brands when viewing comparative versus noncomparative ads. Brands advertised in a comparative format were shown to be more likely to be perceived as similar to the leading brand than brands advertised in a noncomparative format.[5]

Comparative Prescription Drug Advertisements

Despite extensive research on comparative advertising of consumer products and a limited number of studies on how DTC ads could help consumers compare drugs[6], very little research has been conducted on comparative prescription drug advertisements,[7] Consequently, it is unclear whether these findings are applicable to comparative drug ads or how such claims influence consumers' perceived efficacy of advertised drugs.

Currently, most DTC ad comparisons focus on drug attributes, such as differences in dosing or administration method.[8] Because few head-to-head clinical trials have been conducted, very few DTC ads include efficacy-based comparisons.[9] The present study aims to investigate how consumers interpret and react to DTC comparative drug ads. Specifically, the study will explore two types of drug comparisons in DTC ads: (1) drug efficacy comparisons and (2) other

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Marketing, 61(4), 1–15; Miniard, P. W., Barone, M. J., Rose, R. L., & Manning, K. C. (1994). A re-examination of the relative persuasiveness of comparative and noncomparative advertising. *Advances in Consumer Research, 21*(1), 299–303.

[5] Droge, C., & Darmon, R. Y. (1987). Associative positioning strategies through comparative advertising: Attribute versus overall similarity approaches. *Journal of Marketing Research, 24*, 377–388; Gorn, G. J., & Weinberg, C. B. (1984). The impact of comparative advertising on perception and attitude: Some positive findings. *Journal of Consumer Research, 11*, 719–727; Iyer, E. S. (1988). The influence of verbal content and relative newness on the effectiveness of comparative advertising. *Journal of Advertising, 17*(3), 15–21.

[6] See, for example, Schwartz, L. M., Woloshin, S., & Welch, H. G. (2009). Using a drug facts box to communicate drug benefits and harms: two randomized trials. *Annals of Internal Medicine, 150*(8), 516–527; Hauber, A. B., Mohamed, A. F., Johnson, F. R., & Falvey, H. (2009). Treatment preferences and medication adherence of people with Type 2 diabetes using oral glucose-lowering agents. *Diabetic Medicine: A Journal of the British Diabetic Association, 26*(4), 416–424.

[7] Mitra, A., Swasy, J., & Aikin, K. (2006). How do consumers interpret market leadership claims in direct-to-consumer advertising of prescription drugs? *Advances in Consumer Research, 33*, 381–387.

[8] Applications for FDA Approval to Market a New Drug, 21 C.F.R. §314.126. (2008). Retrieved from http://edocket.access.gpo.gov/cfr_2008/aprqtr/pdf/21cfr314.126.pdf

[9] Mitra, A., Swasy, J., & Aikin, K. (2006). How do consumers interpret market leadership claims in direct-to-consumer advertising of prescription drugs? *Advances in Consumer Research, 33*, 381–387.

evidence-based comparisons, such as dosing, mechanism of action, and indication. The study findings will inform FDA of relevant consumer issues relating to comparative DTC advertising.

2. Purpose and Use of the Information Collection

The present study aims to investigate how consumers interpret and react to DTC comparative drug ads. Specifically, the study will explore two types of drug comparisons in DTC ads: (1) drug efficacy comparisons and (2) other evidence-based comparisons, such as dosing, mechanism of action, and indication. The study findings will inform FDA of relevant consumer issues relating to comparative DTC advertising.

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 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

Despite extensive research on comparative advertising of consumer products, very little research has been conducted on comparative prescription drug advertisements.[10] Consequently, it is unclear whether these findings are applicable to comparative drug ads or how such claims influence consumers' perceived efficacy of advertised drugs.

[10] Mitra, A., Swasy, J., & Aikin, K. (2006). How do consumers interpret market leadership claims in direct-to consumer advertising of prescription drugs? *Advances in Consumer Research, 33,* 381–387.

Currently, most DTC ad comparisons focus on drug attributes, such as differences in dosing, administration method, or risks.[11] Also, very few DTC ads include efficacy-based comparisons.[12] Nevertheless, a limited number of studies have explored how DTC ads can help consumers compare drugs.

One study examined whether adding a drug facts box to DTC ads improved the accuracy of perceived efficacy of two alternative drugs.[13] The results showed that the drug facts box improved consumers' knowledge of drug benefits and side effects. This may lead to better decision-making between the drugs for current symptoms and correcting earlier overestimations of efficacy.

Another study involved a discrete-choice experiment in which patients with type 2 diabetes were offered a series of pairs of hypothetical treatment profiles and were asked to choose between the two hypothetical drugs (Hauber, Mohamed, Johnson, & Falvey, 2009). Each profile was described by a set of medication characteristics with varying levels. The study examined treatment preferences and likelihood of medication adherence to the hypothetical drugs. The results showed that while patients thought glucose control was important, medication side effects and risks also influenced patients' treatment choices.

Given these past studies, it appears there is adequate background literature but no studies that duplicate the efforts proposed in this statement.

5. Impact on Small Businesses or Other Small Entities

[11] Applications for FDA Approval to Market a New Drug, 21 C.F.R. §314.126. (2008). Retrieved from http://edocket.access.gpo.gov/cfr_2008/aprqtr/pdf/21cfr314.126.pdf

[12] Mitra, A., Swasy, J., & Aikin, K. (2006). How do consumers interpret market leadership claims in direct-to consumer advertising of prescription drugs? *Advances in Consumer Research, 33*, 381–387.

[13] Schwartz, L. M., Woloshin, S., & Welch, H. G. (2009). Using a drug facts box to communicate drug benefits and harms: two randomized trials. *Annals of Internal Medicine, 150*(8), 516–527.

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

A 60 day Federal Register Notice was published in the *Federal Register* on July 1, 2011, vol. 76, No. 127; pp. 38663-38666 (see Appendix A). FDA received two public comments. One commenter failed to attach any comment, and the other commenter discussed issues far outside the scope of the proposed research (i.e., about morning-after contraception).

External Reviewers

In addition to public comment, DDMAC sent materials and received comments from three individuals for external peer review. These individuals are:

- David Brinberg, Ph.D., Virginia Tech University
- Jeremy Kees, Ph.D., Villanova University
- Steven W. Kopp, Ph.D., University of Arkansas

9. Explanation of Any Payment or Gift to Respondents

Internet panel participants receive points for completing a survey. One thousand 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. (For the households provided Internet appliances and an Internet connection, their incentive includes the hardware and Internet service in addition to the sweepstakes entries and bonus points). Traditionally, panelists earn sweepstakes entries on some surveys (including surveys more than 15 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). 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 with an assurance of privacy to the extent allowable by law. The study instructions will include information explaining to respondents that their information will be kept private to the fullest extent allowable by law. In addition, 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 American Marketing Association, the Council of American Survey Research Organizations, and others.

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

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

The total annual estimated burden imposed by this collection of information is 3,290 hours for this one-time collection (Table 1).

Table 1.--Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)[2]	Total Hours
Screener	19,120	1	19,120	02/60	637
Pretests	750	1	750	20/60	250
Questionnaires	7,060	1	7,060	20/60	2,353
Total					3,240

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

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

Table 3. --Estimated Annualized Burden Costs			
Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
General public	3,240	$18.68[1]	$60,523
Total			$60,523

[1]Based on the 2010 median weekly income of $747 for both sexes, as reported by the Department of Labor, ftp://ftp.bls.gov/pub/special.requests/lf/aat39.txt

13. Estimates of Other Total Annual Costs to Respondents and Record Keepers

There are no costs to respondents. There are no record keepers.

14. Annualized Cost to the Federal Government

The total estimated cost to the Federal Government for the collection of data is $1,482,034 ($454,011 per year for three years). This includes the costs paid to the contractors to create stimuli, program the study, draw the sample, collect the data, and create a database of the results ($1,362,034). 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, to analyze the resultant data, and to draft a report ($120,000; 15 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 experimental data, such as descriptive statistics, analysis of variance, and regression models, will be used to analyze the data. See section B below for detailed information on the design, hypotheses, and analysis plan. The Agency anticipates disseminating the results of the study after the 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 posting.

Table 4. Project Timetable

Task	Estimated Completion Date
External Peer Review	October, 2011
RIHSC Review	November, 2011
30-day FR notice publication	December, 2011
OMB Review of PRA package	June, 2012
Data Collection	July/August, 2012
Receipt of Data and Methods Report from Contractor	October, 2012
Data Analysis	January, 2013
Draft Report	March, 2013
Internal Review of Draft Report	April, 2013
Revisions	May, 2013
Final Report	June, 2013

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 certificatio