



October 19, 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2007N-0321, “Experimental Evaluation of the Impact of Distraction On Consumer Understanding of Risk And Benefit Information in Direct-to-Consumer Prescription Drug Broadcast Advertisements”

To Whom It May Concern:

Prescription Access Litigation, LLC (“PAL”),¹ submits the following comments to the U.S. Food & Drug Administration (“FDA”) concerning the proposed study referenced above. PAL is a project of Community Catalyst, Inc., and a coalition of over 130 non-profit organizations, including consumer and health care advocacy groups, senior citizens organizations, labor unions, union benefit funds, non-profit health plans, and other organizations whose goal it is to make prescription drugs more affordable for consumers by using class action litigation and public education to bring an end to illegal pharmaceutical price inflation. The following organizations that are members of the PAL coalition join us in these comments:

- AFSCME (American Federation of State County & Municipal Employees)
- AFSCME District Council 37 Health & Security Plan (NY)
- Alliance for Retired Americans
- Annie Appleseed Project (FL)
- Breast Cancer Action (CA)
- Brooklyn-Wide Interagency Council of the Aging, Inc. (NY)
- Center for Medical Consumers (NY)
- Central New York Citizens in Action Inc. (NY)

¹ PAL previously submitted written comments to the FDA on the topic of Direct to Consumer Advertising on November 2, 2005. Those comments argued for strengthening the DTCA oversight and enforcement rules of FDA generally, and are available at www.fda.gov/ohrms/dockets/dockets/05n0354/05N-0354_emc-000062-02.pdf.

- Citizen Action of New York (NY)
- Congress of California Seniors (CA)
- Connecticut Citizen Action Group (CT)
- Consumers for Affordable Health Care (ME)
- Florida Alliance for Retired Americans (FL)
- Florida CHAIN (FL)
- Government Accountability Project (DC)
- Health & Welfare Trust Fund IUOE Local 877 and 70 (MA)
- Health Care For All (MA)
- Joint Public Affairs Committee for Older Adults (JPAC) (NY)
- Minnesota Senior Federation (MN)
- North Carolina Fair Share (NC)
- Patients not Patents (DC)
- Progressive Research And Action Center (NY)
- Sergeants Benevolent Association (NY)
- TeamstersCare (MA)
- Universal Health Care Action Network of Ohio (OH)
- WIN Senior Action Coalition (WI)

Introduction

Consumer groups, physicians and health care payers have long expressed concerns that direct-to-consumer advertising (DTCA) by pharmaceutical companies drives up the cost of prescription drugs and leads to inappropriate use. Spending on DTCA has gone up consistently since 1997, the year in which the FDA permitted DTC ads to substitute the “brief summary” requirement with the so-called “major statement,” paving the way for ubiquitous drug ads on television. A recent article in the *New England Journal of Medicine* reported that while spending on pharmaceutical promotions (targeted to both consumers and physicians) increased by 330% (\$11.4 billion to \$29.9 billion) between 1996 and 2005, FDA regulatory letters to prescription drug manufacturers fell from 142 in 1997 to 21 in 2006.² The obvious conclusion is that while prescription drug advertisements have flourished, regulation and enforcement of the rules regarding such ads has all but disappeared. An examination of the few regulatory letters issued for violative DTC ads between 1997 and 2006 showed that 84% of them were cited for either

² *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, N. Eng. J. Med 357:7, 673 (August 16, 2007).

minimizing risks (e.g., minimizing or omitting information on side effects), exaggerating effectiveness (e.g., portraying the indication too broadly or making unsubstantiated claims of superiority over other drugs), or both.³

PAL and our members have been sharply critical of DTCA and its effects on consumers' impressions and usage of prescription drugs and on doctors' prescribing patterns. We support significantly increased restrictions on DTCA, such as those we proposed in our testimony before the FDA on November 2, 2005.⁴ As long as drug ads continue to be a staple of modern television viewing, every step possible must be taken to ensure that such ads do not deceive consumers or deprive them of an accurate understanding of the benefits and risks of the drugs advertised.

One key step is increased enforcement. As of the date of these comments, the FDA has issued only one enforcement letter in 2007 concerning a DTC ad – a “reminder ad” for the sleep aid Rozerem. This is an historic low in such enforcement. Hopefully the expanded powers granted to the FDA under the recently enacted FDA Amendments Act of 2007 (ad review fees to increase staff, and the ability to impose fines for violative ads) will embolden the agency to step up monitoring and enforcement of DTCA.

Another important step is to increase the FDA's understanding of how consumers receive, interpret and understand information contained in DTC ads. Given the complexity of modern drug ads, and the many competing elements in such ads, the effect of these ads on consumer beliefs and behavior is not self-evident, but deserves study. Thus, we fully support the FDA's

³ *Id.*, at 677. For example, the FDA found that an Eli Lilly ad for Strattera was false or misleading because it inadequately communicated the indication for the drug by means of competing visuals, graphics and music presented concurrently. Risk disclosures were minimized for Strattera by distracting visuals and graphics including erratic camera movement, quick scene changes and visual changes in point of view. Also, the FDA said a Pfizer print ad for Zoloft was false or misleading relating to the risk of suicidality in patients. See *id.*

⁴ *Supra*, note 1.

decision to study the effect of DTCA on consumers, and, based on the results, hopefully change or increase its enforcement to better carry out its duties under the law.

The FDA requested comments on the following questions regarding its proposed study:

- 1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;
- 2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- 3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- 4) Ways to minimize the burden of the collection of information on respondents.

PAL's comments address the first and third topics.

I. The Proposed Collection of Information is Necessary for the Proper Performance of the FDA's Functions and will have Practical Utility if the FDA Takes Further Action and Strengthens Its Regulatory Authority in Accordance with its Findings.

The FDA should take seriously its duty to enforce its requirement that advertising claims about a prescription drug include a "fair balance" of information about the benefits and risks of advertised products, in terms of both content and presentation.⁵

To the extent the proposed study will help the FDA determine whether visuals presented onscreen interfere with consumers' understanding and processing of the risk information in the ad's audio or text, PAL supports the study's design. The study's focus on the effect of competing and compelling visuals on the consumer's ability to consider and encode risk information is a worthy goal. It is not, however, an end in itself. The proposed study will only be a worthwhile undertaking if it is one component of a larger study, or the first in a series of studies, to understand the effects of different components of drug advertising on consumer risk comprehension and retention. Findings produced from this particular study in isolation would be

⁵ Notice, Docket No. 2007N-0321, Fed. Reg. at 47051 (August 22, 2007).

of little use or impact if they were not supplemented by other studies exploring the full range of issues related to how such ads inform or fail to inform consumers.

II. The Quality, Utility and Clarity of the Information Collected can be Enhanced by Adopting Certain Amendments to the Proposed Test Methodology.

While the study as designed is likely to produce valuable information, that value will be greatly increased if a number of changes are made to the study design. Specifically,

1. The study design fails to account for the complexity of modern drug ads, and should include additional variables and factors to properly simulate actual ads;
2. The limits placed on eligibility are arbitrary and will unnecessarily exclude important subsets of the population from the sample of consumer attitudes; and
3. The Chinese character chosen as neutral stimuli is in fact not neutral under current conditions and may taint consumer attitudes towards the ad.

1. The study design fails to account for the complexity of modern drug ads.

The study is designed to examine the effects on consumers' abilities to process risk information during two scenarios:

- 1) written text stimulus plus audio stimulus
- 2) visual images plus audio stimulus

While studying the interplay of audio and visual stimuli may be valuable to assess risk absorption, it neglects to consider the very subtle and powerful events taking place in today's drug advertisements. The test's current design oversimplifies the post-modern complexity of prescription drug ads. Therefore, in addition to the current test, we recommend that additional variables be included to account for some of the other events taking place in the drug ad. These may include:

Pacing. The pacing of the information in today's drug advertisements has been sped up. The study should consider speed as a factor in the consumer's retention of risk information. The test should be designed to vary the speed of the information in the drug ad and study the subject's retention of risk information at the various speeds.

Placement of Written Text. The announcement of the study merely says that "It will have three conditions: 'reinforcing' text, 'competing' text and a 'control' condition with no text." The design says nothing about the placement or visual prominence of the text. We recommend that this placement and prominence be varied. For example, some participants could be shown ads with "static" text that just appears on the screen in a fixed position, whereas other participants could be shown "scrolling" text. The location, color, font and font-size of the text on the screen are also important variables that inevitably affect consumer perception. These variables should be studied, either in this study or in a future study.

In addition to these proposed changes for the current study, we recommend a number of tests for future studies. We are not recommending these for the current study because the inclusion of too many variables would render the study overly complicated or necessitate a much larger group of participants. The future tests we propose are:

Repetition. A central feature of drug marketing is the frequent repetition of ads and the resulting brand recognition. We suggest that a future study test the effect on risk retention and consumer attitudes of the subjects viewing the ad over and over again.

Images. Drug ads commonly feature actors who do not appear to suffer from the condition that the advertised drug is supposed to treat, portray them as healthier and happier than patients with the condition in question are likely to be, or show them engage in activities unrelated to the drug or condition (what we call the "frolicking through fields of flowers" effect).

A future test should vary the imagery used in sample ads, such as having one sample showing a realistic patient engaged in an activity that is actually related to their condition (e.g. a patient with hypertension using a blood pressure cuff, or a diabetic testing their blood sugar), one showing a realistic patient engaged in a neutral activity, and one showing an apparently healthy patient (i.e. one that appears not to suffer from the condition) engaged in an activity that is wholly unrelated to the condition (e.g. skydiving, in an ad for a toenail fungus drug) The effects of the varying images on participants' comprehension and retention of the risk and benefit information could then be studied.

Music. Just as this study attempts to glean the effect of distracting, consistent and neutral visuals on participants' perceptions, a future test should study the effect of various styles of jingles or music played during the disclosing of risk information – varying such factors as tempo, volume, style of music and the presence or absence of lyrics.

These suggestions only scratch the surface of the numerous different factors at play in modern drug ads that impact consumer perceptions. We encourage the FDA to consult with experts in marketing, linguistics, psychology and other relevant disciplines to come up with and design further studies.

2. The limits placed on eligibility are arbitrary and will unnecessarily exclude important subsets of the population from the sample of consumer attitudes.

The study's design includes the following limitations: 1) Consumers must be over forty years old; 2) Participants must speak English as their primary language; 3) Individuals who can read Chinese are not eligible; and 4) the sole condition chosen for the study is high blood pressure.⁶

⁶ See Notice, 47052.

While consumers over forty (and particularly those over 65) likely consume a majority of the prescription drugs dispensed, increasing numbers of people under 40, including children⁷ are both growing users of prescription drugs and targets of drug ads. Drug ads appear on every type of television station, during virtually all types of programming, at all times of the day and night. Thus, people of all ages see and are influenced by drug ads. To limit the study population to consumers over 40 is thus arbitrary and will result in skewed conclusions of consumer perceptions. In fact, perceptions are likely to vary by age, a variable that the study should account for and document. It is likely that consumers under 40, raised on a different media diet than those over 40, will have different reactions to the same ad than those over 40. The study, therefore, should include a wide array of age groups, from 18 on up.

The requirement that participants speak English as their primary language is troubling because it excludes some of the nation's most vulnerable consumers. Millions of consumers with limited or no English proficiency⁸ are influenced by drug ads despite the fact that English is not their primary language. In fact, for such individuals, the impact of a poorly designed ad with conflicting visual elements is even more serious than for primary-English speakers – they may form a strong positive impression about the drug from the imagery, and yet glean none of the essential risk and side effect information that is either read in a voiceover or shown as text on the screen. This population is too large and too important to exclude from the sample in this test. Therefore, the eligibility criteria should either not exclude people whose primary language is not English or a future test should specifically study the perceptions of people with little or no English speaking ability.

⁷ Consider, for example, Eli Lilly winning FDA approval to market their anti-psychotic drug Zyprexa to teen-agers. See *Lilly's Zyprexa Poised for Approval for U.S. Teens*, Bloomberg.com (9/26/2007).

⁸ According the Migration Policy Institute, the 2000 U.S. census reported that over 21 million individuals in the U.S. did not speak English well or at all.

Furthermore, the exclusion of Chinese-speakers cuts out a large subset of the U.S. population that may develop attitudes about a particular drug ad but not an appreciation for risk information. According to the 2000 U.S. Census, Chinese⁹ is, for the first time, the second-most common foreign language spoken by those living on U.S. soil. Today an estimated 2 million Americans regularly speak Chinese at home.¹⁰ The Chinese-speaking population is a growing and important subset of American consumers who form attitudes about drug ads. The only reason for such exclusion is the use of Chinese symbols, a use which we advise against for entirely separate reasons in the following section. Therefore, both this and future studies should not exclude Chinese speakers.

Finally, the use of high blood pressure as the test's condition will not adequately measure the perceptions of consumers under 40, whose participation we recommended above. To ensure that all test subjects form a real attitude about the test ad, the condition chosen should be one that people of all ages are susceptible to. Alternatively, the study's test ads could use a made-up condition and made-up drug. The condition can be broad in its scope, effecting all age groups and ethnicities equally and therefore greatly expand the scope of eligible test subjects.

3. The use of the Affect Misattribution Procedure employing a Chinese symbol as the neutral character may taint the results of the test, given recent consumer fears about products made in China.

The Federal Register notice announcing the study states:

due to the nature of one of our measures requiring a set of neutral stimuli, which we have designated as Chinese characters, it will be necessary for us to eliminate individuals who can read Chinese.¹¹

The use of Chinese characters as neutral stimuli and as a basis to assess participant's attitudes towards the ad may severely taint the data, given the spate of recent news concerning unsafe or

⁹ Including both Mandarin and Cantonese.

¹⁰ *Chinese At Home - increasing number of Chinese-speaking Americans*, American Demographics, February 2003.

¹¹ See Notice at 47052.

tainted products that were made in China, including pet food, toys containing lead paint and even unsafe prescription drugs.¹² A new poll conducted at American University found Americans don't trust drugs bearing a "Made in China" or "Made in India" label.¹³ Though 88 percent of those polled said they thought drugs made in the U.S.A. are safe, only 14 percent trusted drugs made by Chinese and Indian manufacturers.¹⁴ Given these attitudes (even if they are unfair or unwarranted) the use of Chinese characters cannot be considered "neutral stimuli." There is a strong likelihood that Chinese characters may skew the perceptions of participants towards the negative. A different neutral stimulus should be used, such as made-up characters that are not from any actual language.

Conclusion

The proposed study will begin to provide valuable insight into how consumers perceive risk information in modern drug ads. We recommend that the changes we have proposed be adopted, and we further recommend that additional studies be conducted. Finally, with the insights gained, we encourage the FDA to use its newly-granted powers to more closely monitor drug advertisements and increase enforcement action against deceptive advertisements.

Respectfully submitted,

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¹² Barboza, David and Wilson, Duff, *Complaint Offers Window on Chinese Drug Ring*, New York Times, (9/28/2007).

¹³ "Prescription Drug Safety: National Survey" Center for Congressional & Presidential Studies, American U. (2007). Study results at dialogueondrugsafety.org/assets/files/AU%20Survey_Drug%20Safety_FINAL%209.20.pdf

¹⁴ Id.