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Commissioner Margaret Hamburg MD
Division of Dockets Management (HFA–305)
Food and Drug Administration
5630 Fishers Lane, rm 1061
Rockville, MD 20852

Re: FDA-2009-N-0582

February 27, 2012

Dear Commissioner,

These comments from Public Citizen Health Research Group (PCHRG) come in response to Docket No. FDA-2009-N-0582, the FDA Proposed Rule: Reopening of Comment Period on Specific Data relating to Direct to Consumer (DTC) Drug Advertisements, published at 77 FR 4273, January 27, 2012.

The above comment period was reopened to allow comment on a study added to the above docket entitled "Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Television Advertisements" (Distraction Study). This study, dated May 2011, was "designed to investigate some advertising factors that could influence consumers' understanding of a drug's risks." [1]

PCHRG previously submitted comments pertaining to the proposed rule published March 29, 2010. [2] To the extent these earlier comments speak to matters raised in the Distraction Study, they are incorporated herein.

We reiterate here our serious concerns about DTC advertising, primarily because it often supplants the knowledge and judgment of the physician in determining whether a particular drug is most suitable for a particular patient. If, despite this concern, DTC advertising is allowed, FDA should require far more reassurance than is now the case that after viewing such commercials, consumers would understand the drug's risks, benefits, and comparability to other pharmaceutical and non-pharmaceutical interventions.

[1] 77 FR 4273(2012), January 27, 2012.

[2] 75 FR 15376 (2010).

This comment, however, will focus primarily on FDA's specific request for guidance concerning the Distraction Study and the role that its findings might play in regulating DTC drug advertising on television.

We believe that while there is strong support both in the Distraction Study and elsewhere for the use of superimposed text accompanying DTC drug advertising on television, this study is so flawed that any conclusions or lack thereof as to the other variables studied would be of negligible value in fashioning a regulation that would adequately protect consumers.

The Distraction Study examined six specific issues relating to consumer understanding of risk information. These issues are most conveniently discussed in three groups.

1. The role of superimposed text (SUPERs) on risk comprehension. Does concurrent presentation of risk concepts in both audio and on screen facilitate processing the "major statement"[3] of risk information? Our conclusion (based not only upon this poorly designed study but upon a wealth of other evidence and experience) is YES.

2. The role of affective tone in risk comprehension. Does the tone of positive visuals in a television ad such as scenes of patients socializing with family and friends or enjoying recreational activities distract viewers from attending to the major statement? Our conclusion is that the Distraction Study, because of its many limitations upon which we shall expand below, gives no useful guidance and therefore must be disregarded.

3. The effect of inconsistent visuals on risk comprehension. Is information processing improved when similar information, such as visual information relating to risks, is presented concurrently with the audio presentation of the major statement? Conversely, is information processing disrupted when conflicting information, such as visual information relating to benefits, is presented concurrently with the audio presentation of the major statement?

[3] The "major statement" is a term that is relevant only to broadcast (TV or radio) ads for prescription drugs. It refers to the presentation of the drug's most important risks. This presentation must be spoken. It also can be included in the video part of TV advertisements. The amount and type of included risk information will vary by drug because different drugs have different risks.
http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072025.htm#M

Here again, our conclusion is that the Distraction Study gives no useful guidance and therefore must be disregarded.

Discussion of the Specific Questions Presented

Question 1 – The role of superimposed text (SUPERs) on risk comprehension.

In its earlier comment, PCHRG strongly urged FDA to follow the practice of the Federal Trade Commission (FTC) in requiring simultaneous on-screen text to accompany video presentations of risk.

The Distraction Study similarly found "strong support" both in the study and, much more importantly, in the literature reviewed, for increased risk comprehension when risk information was presented in text simultaneously with the audio channel. We therefore reiterate our earlier endorsement of following FTC practice of simultaneous on-screen text accompanying audio risk information and urge the FDA to follow this practice as well.

Furthermore, despite the finding of only marginally greater risk comprehension with large SUPERs as opposed to small SUPERs, we would nevertheless support the use of large text, inasmuch as the study did not control for age, visual acuity, and size of television screen normally viewed by subjects. Also, this study involved advertisements viewed on a computer screen, where the consumer is typically seated close up and can easily lean in for a better view. Results cannot be generalized to the context of television advertising, where the consumer is typically seated farther away and cannot adjust themselves as easily.

We also note that in the Distraction Study, both the large SUPER and small SUPER groups viewed text that was easy to read in some contexts: the text read by the small SUPER group took up approximately 7% of the screen, meaning that even in the small SUPER group the text would be .84 inches in height when presented on a 12-inch screen. The text read by the large SUPER group was twice as large.[4] Also, in both conditions the text was presented on a black banner that filled approximately 1/5 of the screen (21%). Therefore even if FDA decides to permit "small" text in broadcast media, the text should be at least as large as 7% of the screen.

It should be stressed, however, that we support text that is larger than 7% of the screen, given the variety of contexts in which the ads may be viewed.

Questions 2 and 3 – The role of affective tone in risk comprehension and the role of risk reinforcing SUPERs in altering the effect of tonally positive visuals (Question 2) , and the effect of inconsistent visuals on risk comprehension (Question 3).

[4] Distraction Study, Page 17

The Distraction Study failed to reach any definite conclusions regarding these questions. We submit that this was because the design of this study itself was so flawed that it no valid conclusions could be reached regarding the role of affective tone and inconsistent visuals on risk comprehension. For this reason, we believe that the Distraction Study should play no role whatsoever in shaping the regulation of DTC drug advertising.

Design Flaws in the Distraction Study.

It is likely that the following design flaws resulted in the failure of the Distraction Study to detect any significant effects upon risk comprehension resulting from various forms of distraction.

A. **The low response rate is questionable**. However random the selections of the initial pool and the distribution of invitations may have been, fewer than 50% of those receiving invitations elected to respond to these invitations. This low response rate could have introduced bias if the characteristics of responders varied between groups. More importantly, the low response rate means that the study results are not generalizable, because it is impossible to determine whether the general population would be more or less distractible than this highly self-selected sample.

B. **The authors failed to demonstrate that the study was adequately powered**.[5] This in turn could have led to falsely negative results. This important issue must be raised because of the limited number of participants in each of the numerous subsections of the study.

C. **The images used in each condition were too highly similar to evoke differing responses.** One set of conditions compared static images of chairs, rocks, and metal arches to static images of a baby with a puppy, a family's hands, and girls jumping with beach balls. The other set of conditions compared bulleted text of risks in front of an exclamation point to bulleted text of benefits in front of a dial. It is not surprising that none of these sets was any more or less distracting than any other. (The study authors admit as much themselves when they point out that their own

[5] The power of a statistical test is the probability that the test will actually detect an effect if one exists. When a test is under-powered due to a small sample size, the chances increase that the test will fail to pick up a statistically significant difference between groups, even though a difference in fact exists.

manipulation checks failed and therefore "it is not surprising that we did not find substantial differences between these conditions regarding risk comprehension.").[6]

It remains to be seen whether other techniques might more effectively elucidate the role of distraction in comprehension of risk. For example, actual drug advertisements often include dynamic footage of happy, healthy, and attractive patients "living their lives" while using the product. Using these more dynamic distracting images would have been far more likely to produce evidence of decreased risk comprehension.

D. **The narrow scope of information provided about the fictional drug offered to the study subjects was inconsistent with the "real world" risk profiles of most prescription drugs.** The prescription drug used in this study was a fictional antihypertensive named "Zintria." Zintria was presented to consumers with a fixed and limited universe of benefits, risks and warnings. Most prescription drugs, including antihypertensives, have much longer rosters of risks and warnings. A thirty- or sixty-second commercial barely has time to cover even the most serious ones, let alone time to compare other products or approaches (including non-pharmacological) for the same condition. Even if there were adequate time, viewers are unlikely to have sufficient background to determine the safety and efficacy as well as the individual appropriateness of a particular drug or other treatment for their particular needs. Therefore, again the study design could not produce results generalizable to real world use of more typical drugs.

<u>Design Flaws in The AMP Study</u>.

In its January 27, 2012 notice, the FDA declined to mention a second study, "A Supplementary Test of Distraction in DTC Advertising Using an Implicit Measure, the Affect Misattribution Procedure" (AMP Study), published by FDA in June 2011. However, the AMP Study was obliquely referenced in the Distraction Study.[7] While the AMP Study asserted it would "show promise with future refinements"[8] we note here only that the AMP Study suffered from similar design flaws as the Distraction Study: the same non-distracting images were used, and participation was actually lower due to technical difficulties. Also, the AMP procedure used in

[6] Distraction Study , Page 31

[7] Distraction Study, Page 13, citing a "supplementary study using an implicit measure of attitudes called the Attitude Misattribution Procedure (Payne et al, 2005)" discussed in a separate report, the AMP Study, dated June, 2011.

[8] AMP Study Page 31

the AMP Study was a novel one that has not been subjected to testing. Earlier AMP testing involved only previously-held, strong beliefs, not new associations with made-up products.

FDA Should Not Rely on the Distraction Study in Better Regulating DTC Drug Advertising on Television.

While a physician must actually prescribe an advertised prescription drug product, there is ample support for the role of patient pressure in increasing the likelihood of prescribing a particular product, even though another product or even no product might have a superior result. This, coupled with the effect of aggressive marketing targeting physicians, practically insures that scrip will be written without adequate regard for important information relating to risk or alternative treatment options.

Direct to consumer advertising may thus supplant the knowledge and judgment of the physician in determining whether or not a patient will wind up using the drug in question. This is one of many reasons for carefully regulating direct to consumer advertising of prescription drugs.

However, if there is to be DTC advertising, we would urge that the nostrum "*primum non nocere*" (first do no harm) apply equally to advertisers as to physicians inasmuch as the influence of the advertiser to varying degrees may otherwise supplant the influence of the physician.

The principle of first doing no harm could be operationalized by requiring television advertisements for prescription drugs to include visuals that focus on risks. At the very least television advertisements for prescription drugs should feature simultaneous audio and large-letter, contrasting color, visual presentations of the labeling including adverse effects, warnings, contraindications, FDA safety bulletins, etc.

We would also advocate requiring a discussion of other treatment alternatives, both pharmaceutical and non-pharmaceutical, (including head-to-head safety and efficacy data, where available, and cost considerations).

Such requirements would likely be unacceptable to sponsors, but we urge FDA to exercise its powers to promulgate regulations based on the reality that lay consumers have a vastly different background than the medical professionals who have been the traditional targets of prescription drug advertising.

Sincerely,

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