



Michael D. Maves, MD, MBA, Executive Vice President, CEO

January 29, 2009

Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Attn: FDA Desk Officer

OMB Control No. 0910-NEW

RE: Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Broadcast Advertisements [Docket No. 2007-N-0451]

The American Medical Association (AMA) strongly supports the Food and Drug Administration's (FDA) proposal to evaluate whether there is fair balance between risk and benefit information in direct-to-consumer (DTC) television advertisements for prescription drugs. In particular, the AMA strongly supports FDA's intent to investigate whether the use of competing, compelling visual information about potential drug benefits interferes with viewers' processing and comprehension of risk information about drugs in DTC television advertising or with their cognitive representations of the drugs.

The AMA previously has expressed concern to both Congress and the FDA that DTC ads shown on television often are very effective at using pleasing and, in our opinion, distracting visuals as the major risk information is being discussed in audio only. Furthermore, we have referenced research that indicates the AMA's concerns have merit. For example, Day and colleagues found that consumers were less able to understand and retain information about side effects and risks of advertised drugs than about indications and benefits because of poor cognitive accessibility of risk information within television DTC advertisements.¹

¹ Day R. Cognitive accessibility of prescription drug information. Presented at the Food and Drug Administration Public Meeting on Direct-to-Consumer Promotion. September 22, 2003. Available at: <http://www.fda.gov/cder/ddmac/DTCmeetingTranscript.doc>. Accessibility verified on February 23, 2006.

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The FDA's proposed study to investigate the impact of visual distraction, as well as the role of textual elements, on consumers' ability to process and comprehend drug risk information presented in DTC television advertisements should provide useful new information.

We agree with the Agency that the results of this study should help improve how television advertisements present a drug's risks and benefits.

The AMA looks forward to the completion of this important study and, as necessary, the translation of its results into more effective DTC regulations.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA