

---

# Assessing the Impact of a Toll-Free Number for Reporting Side Effects in Direct-to-Consumer Television Ads: Proposed Study Design

Kathryn J. Aikin, Ph.D.  
Social Science Analyst  
Division of Drug Marketing, Advertising and  
Communications, FDA  
Risk Communication Advisory Committee  
Meeting

May 16, 2008

# Presentation Outline

---

- Public Comment Process for Federal Research
- Current Legislation and Other Relevant Background
- Research Questions and Draft Study Design



# Food and Drug Administration Amendments Act of 2007 (FDAAA)

## Sec. 906 STATEMENT FOR INCLUSION IN DIRECT-TO-CONSUMER ADVERTISEMENTS OF DRUGS.

- (a) PUBLISHED DIRECT-TO-CONSUMER ADVERTISEMENTS.---  
Section 502(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352), as amended by section 901(d)(6), is further amended by inserting “and in the case of published direct-to-consumer advertisements the following statement printed in conspicuous text: ‘You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.’” after “section 701(a),”.
- (b) STUDY.---
- (1) IN GENERAL.--- In the case of direct-to-consumer television advertisements, the Secretary of Health and Human Services, in consultation with the Advisory Committee on Risk Communication under section 567 of the Federal Food, Drug, and Cosmetic Act (as added by section 917), shall, not later than 6 months after the date of the enactment of this Act, conduct a study to determine if the statement in section 502(n) of such Act (as added by subsection (a)) required with respect to published direct-to-consumer advertisements is appropriate for inclusion in such television advertisements.

# Food and Drug Administration Amendments Act of 2007 (FDAAA), con't.

---

- (2) CONTENT.--- As part of the study under paragraph (1), such Secretary shall consider whether the information in the statement described in paragraph (1) would detract from the presentation of risk information in a direct-to-consumer television advertisement. If such Secretary determines the inclusion of such statement is appropriate in direct-to-consumer television advertisements, such Secretary shall issue regulations requiring the implementation of such statement in direct-to-consumer television advertisements, including determining a reasonable length of time for displaying the statement in such advertisements. The Secretary shall report to the appropriate committees of Congress the findings of such study and any plans to issue regulations under this paragraph.

# Other Relevant Background

---

- Best Pharmaceuticals for Children Act (Public Law 107-109, January 4, 2002)
  - Section 17 required FDA to issue a final rule requiring the addition of a statement to the labeling of each drug product for which an application is approved under section 505 of the Act. Under the BPCA, the statements must include: (1) a toll-free number maintained by FDA for the purpose of receiving reports of adverse events regarding drugs; and (2) a statement that the number is to be used only for reporting purposes, and it should not be used to seek or obtain medical advice (the side effects statement).

# Focus Group Findings

---

- Some of the high school educated or less group thought that the statements instructed them to call FDA for medical help.
- Some participants in both groups understood the statements, but said they were not motivating enough to cause them to call FDA's toll-free number in the event that they might experience an adverse side effect.
- Some participants in both groups understood the statements and said they would call FDA to report adverse side effects if serious enough.
- Many suggested the addition of a Web site to report adverse side effects.

# Research Questions for Committee

---

- Does the inclusion of a toll-free number for reporting side effects in DTC television advertisements detract from the communication of important risk information in the ad?
- If the statement does not detract from the communication of important risk information, what is the optimal length of time this statement should be displayed in the ad?

# Proposed Design

	Duration in SUPER	
	Short	Long
Placement		
Before Major Statement of Risks		
During Major Statement of Risks		
After Major Statement of Risks		

+

Control (no toll-free statement)

+

Extra Prominent (after Major Statement of Risks, toll-free statement in both SUPER and Voiceover)

# Proposed Sample

---

- Gender:
  - Roughly equal distribution of men and women
    - At least 40% but not more than 60% men in each condition
- Age:
  - Must be 21 years or older
  - Spectrum of ages from 20s to 80s
  - No more than 15% under age 25 in each condition
  - At least 40% over age 55 in each condition
- Education:
  - Spectrum from less than high school graduate to post graduate education
  - No more than 30% with advanced degrees (i.e., Master's, Ph.D., J.D., M.D., etc.)
  - At least 15% with high school education or less (including people who have completed high school with diploma or GED or who have some high school but have not completed high school)

# Research Questions for Committee

---

- Does the inclusion of a toll-free number for reporting side effects in DTC broadcast advertisements detract from the communication of important risk information in the ad?
  - Will the proposed study address this question?
- If the statement does not detract from the communication of important risk information, what is the optimal length of time this statement should be displayed in the ad?