FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF REQUEST FOR DATA TO SUPPORT SOCIAL AND BEHAVIORAL RESEARCH (0910-0847)

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TITLE OF INFORMATION COLLECTION: Study of Comparative Effectiveness of Disease Education Messaging

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   The FDA's *Strategic Plan for Regulatory Science* identifies nine priority areas in which new or enhanced engagement in regulatory science research is essential to advancing its regulatory mission. One of these priority areas is to *Strengthen Social and Behavioral Science at FDA by Enhancing Audience Understanding*. Additionally, FDABAA-17-00123 aims to, in part, "…develop tools for measuring effectiveness of messages that are being communicated to the public by industry advertisements and by FDA communications."

   Selection of a messenger, or spokesperson, to communicate health messages to the public should follow an evidence-based approach. Celebrity spokespersons have long been used in public outreach, education efforts, and advertising regarding disease awareness and therapeutic agents, with the premise that celebrities would be more effective than traditional health authority figures in conveying the desired health messages. However, there are few primary studies evaluating celebrities' impact on health, and there are perhaps no studies contrasting the effectiveness of different categories of messengers in a controlled trial. Furthermore, data are lacking for the magnitude of influence of celebrities on health decisions, and what the conditions are that mediate influence across different contexts. A better understanding of this information can help FDA improve how it conveys messages to the public.

   To further understanding of the influence of spokesperson type on message efficacy, WebMD Health Corp. (WebMD) will use its research capabilities and targeted access to WebMD.com consumer website visitors to measure the comparative effectiveness of a message delivered by a celebrity, by an expert from a recognized academic institution, and by an expert from a federal health agency.

2. **Intended use of information:**

   The results of this study will be used to inform future communication strategies for FDA. Though this research will study efficacy of messaging pertaining to a disease state, the results of this study may further inform effective risk communications.

3. **Description of respondents:**

   WebMD website visitors and newsletter subscribers who are likely patients or caregivers in the studied disease state (cancer) will be targeted by WebMD and driven to the relevant disease educational materials using personalized content.

A control arm (n = 400) will survey visitors to the WebMD health topic website who are not exposed to the educational materials. The exposed arm (n = 1200) will consist of visitors who view one of the educational materials. Respondents in the exposed arm will be randomly intercepted after engaging with educational material and asked to participate in a survey.

4. **Date(s) to be conducted:**

   March 19, 2018 to September 14, 2018

5. **How the information is being collected:**

   As with other survey research studies conducted by WebMD, precise targeting strategies will incorporate WebMD website visitor data and analytics to identify audiences of patients and caregivers who have an active interest in the disease state. WebMD capitalizes on users' self-selected interest in specific topics and areas of the WebMD website plus disease-topic newsletter registrations, as well as retargeting of visitors who navigate to other sections of the WebMD website. WebMD also behaviorally targets visitors based on user engagement patterns by, for example, targeting visitors who interact with specific topics (including comorbid conditions) and are thus more likely to consume content in corresponding areas of the site.

   Upon landing at the educational materials, the targeted visitors will be randomly recruited via an interstitial invitation to a brief research study. Balanced inclusion by gender, age group, and other relevant characteristics will be ensured by initial screening questions.

6. **Confidentiality of respondents:**

   All respondents are subject to WebMD's privacy policy, and will be given a link to the privacy policy before taking the survey. WebMD does not share personally identifiable information ("Personal Information") for government projects. Respondent identity and information will remain private to the extent permitted by law.

   As a nationally known organization, WebMD takes privacy and security extremely seriously. WebMD utilizes a multi-layered approach to security by implementing security controls at the physical, network, system, and application levels.

7. **Amount and justification for any proposed incentive:**

   No honoraria or incentives will be offered for survey participation.

8. **Questions of a sensitive nature:**

   The survey contains questions regarding whether the respondent has personally been diagnosed with, cares for someone with, or has a loved one who has been diagnosed with cancer. For respondents who answer affirmatively, subsequent questions ask about the diagnosis and prognosis.

9. **Description of statistical methods:**

Key performance indicators (KPIs) will be tested by comparing:

- Celebrity, academic institution, and government experts
- Text article and video
- Interactive effects, if any, across the two factors above, such as "Celebrity and video," "Medical experts with text article," etc.

A statistical significance test at a 95% Confidence Level will be applied to examine the KPI's effect size difference for the types of materials (text and video) for the presentation agents (celebrity, institution, and government experts). Multivariate models may be used to determine and compare the mediating effects of hypotheses for media impact (hypothesis: the information presentation methods generate different levels of feeling of "control" and "empowerment") and self-efficacy (hypothesis: the level of control and empowerment will increase the likelihood to take initiatives about their health) on future behaviors. A comparison with the control group will demonstrate the contribution of the educational materials on attitudes, motivations, anticipations, and behavioral modifications.

BURDEN HOUR COMPUTATION:

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Exposed arm	1,200	10	200
Control arm	400	10	67
Total	1,600		267

REQUESTED APPROVAL DATE: 2/12/2018

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