FDA DOCUMENTATION FOR THE GENERIC CLEARANCE, "Testing Communications on Drugs" (0910-0695)

TITLE OF INFORMATION COLLECTION: Rapid Message Testing with Consumer Panel — Additional Testing of Drug Safety Communications About Misuse and Abuse of Over-the-Counter Medications

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. **Statement of need:**

   FDA releases information about safety issues with the drugs the Agency approves. This includes the misuse and abuse of these regulated products. In an effort to better understand whether there are potential unintended consequences related to these types of communications, particularly the recreational use of easily obtainable over-the-counter (OTC) medications, this project will ask consumers if they know, and how they learn about, non-medical use of these products and obtain their reactions to related FDA communications.

   The communications that will be used as examples for this project are three Drug Safety Communications (DSCs). DSCs are FDA's primary tool for communicating important new and emerging drug safety information to the public. DSCs represent FDA's independent scientific analyses of a drug safety issue and our communication of that information to the public. Each DSC is distributed to more than a million listserv subscribers and social media followers, and is viewed many thousands of times on our website alone.

   We plan to test DSCs on two products that have already been posted to the FDA website, Imodium (June 2016) and Benadryl (September 2020), and a third DSC about a fictitious nasal decongestant product based on anecdotal information we have received. For the latter, we are using the fictitious product name Nasadrine during testing because the information is not yet public. Although these three DSCs are the focus of this testing, the findings will be of use more generally in ways that can be applied to other types of FDA communications and various other OTC products. The findings will help FDA better understand any potential negative consequences related to communicating about non-medical/recreational use of FDA-regulated drugs.

   FDA tested these communications with a small sample of consumers under OMB Control Number 0910-0695 in December 2020. This small sample was intended to include nine participants who had used OTC or prescription medicines for non-medical or recreational purposes and nine participants who had not. However, due to participant misunderstanding of the screener questions, those recruited as recreational users had only used medicines as a sleep aid and did not have experience abusing or misusing these products. The first round of testing provided useful insight into the perspectives of non-users, but FDA would now like to conduct an additional round of testing with the nine recreational users it originally sought to include.

FDA has revised its screener questions and now proposes to recruit consumers who have used OTC or prescription medicines "just to get high or for fun." McNeely et. al (2014) found that while most cognitive interview participants understood recreational use to mean "to have fun," "get high," or "party with," some misinterpreted the term "recreationally" to mean "occasionally" or drew a distinction between recreational use being a want and addiction being a need. FDA's revisions to the screener questions use participants' own words uncovered in this 2014 study to avoid further misinterpretation during recruitment and better target respondents of interest.

Communications science tells us that we must test messages with our intended audiences. Thus, FDA plans to test these communications using cognitive interviews with a small sample of nine U.S. adults drawn from a diverse consumer panel.

This data collection is the 21st in a series of FDA rapid message tests with consumers submitted to OMB under generic clearance. These projects are part of FDA's effort to make consumer testing part of its routine communication development processes. This project is in keeping with the spirit of the 2015 Executive Order[1] to improve how information is presented to consumers by applying behavioral science insights, and it meets repeated calls from FDA's Risk Communication and Advisory Committee to conduct message testing with targeted samples of the general public.

2. **Intended use of information:**

FDA's contractor Westat will test the form with a small sample of target audience members to ensure the message meets its objectives without causing unintended negative effects. FDA's Risk Communication and Advisory Committee includes renowned experts and researchers in social sciences, marketing, health literacy, and related fields. From its very first meeting in 2008, the Committee has consistently advised and reaffirmed that testing communications with the target audience is necessary for FDA, and that using small samples is an effective approach for testing and communicating in a timely manner. In fact, research has shown that "saturation," or the point at which no new information or themes are observed, can occur with as few as 12 interviews, as described in Guest et al (2006).

FDA will use the collected interview data to refine its messaging by improving the comprehensibility and personal relevance for a higher public health impact. Specifically, FDA is asking Westat to gain insight to the following questions:

- What have participants read, seen or heard about non-medical/recreational use (misuse/abuse) of OTC medications?
- From what source(s) have participants read, seen, or heard this information?
- Have participants ever sought out information, considered using, or used any OTC or prescription medications for non-medical/recreational use? If so, which ones and why?
- What are participants' initial overarching thoughts about FDA's communications about the misuse/abuse of Benadryl? Imodium? Nasal decongestants?

[1] https://obamawhitehouse.archives.gov/the-press-office/2015/09/15/executive-order-using-behavioral-science-insights-better-serve-american

- Why do participants think FDA is communicating about each of these products/issues?
- Do participants indicate that any of the FDA information is new to them?
- What is the main message that participants get from each communication?
- How do each of these communications make participants feel (e.g., concerned about using these products generally, even with indicated use/dosages; unconcerned because they wouldn't misuse/abuse these products; curious and/or encouraged about non-medical use) and why?
- How likely do participants feel these FDA communications would encourage recreational use and why?
- What was it in the communications that caused participants to be curious or encouraged?
- What would participants think or do after reading each of these communications, and why?
- What information is missing or would be helpful to add to address the potential to encourage non-medical use? Why would this information be helpful?
- Is there anything else participants suggest FDA think about when communicating about these kinds of safety issues?

The data collected will not be statistically representative of the target audience population. Therefore, the data will not be used for making policy or regulatory decisions.

3. **Description of respondents:**

We will conduct nine 45-minute interviews with U.S. adults. Westat has partnered with Plaza Research, a recruitment specialist to recruit respondents from its general population panel. Plaza Research tracks and stores all database member activity and assigns a unique ID number which stays with the member throughout their entire membership. These tracking records consist of profile information provided during enrollment, profile updates, and past focus group or in-depth interview involvement. Plaza monitors the quality of their data through various quality checks to save time and provide confidence in data accuracy. These quality checks include individual vetting of contact information, and review of enrollment data, as well as review of screener questions, rescreening of participants before participation, and client feedback on past focus group and interview response.

We will use a participant screener to recruit consumers who have ever used an OTC or prescription medicine "just to get high or for fun." Participants will be 18-28 years old (an age group more inclined to engage is risky behaviors) with lower education (primarily high school or less). To the extent possible, the participant pool will be diverse in terms of gender, race/ethnicity, and geography.

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

We plan to conduct interviews in March, 2021.

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

We will conduct all interviews remotely using telephone and screen sharing technology with participants on web-enabled devices such as desktop computers, laptops, or tablets. We will ensure that any materials provided to the participants for the test are compatible with these devices. We will email materials to participants who do not have access to screen sharing technology.

For each 45-minute interview, a trained interviewer will lead the discussion using a semi-structured interview guide that ensures consistency in major topics but allows flexibility in probing each participant on particular questions.

Note takers will chart their findings into a standardized reporting template so that all notes are organized in a consistent manner. Interviewers will review the notes to ensure accuracy. With the consent of participants, we will audio record each interview.

FDA staff will have the ability to listen to the interview sessions, and this will be made known to participants as part of the informed consent.

6. **Confidentiality of Respondents:**

We will provide all respondents with informed consent language that ensures they understand the project purpose, that their participation is voluntary, and that their responses will be kept secure to the extent permitted by law. As part of the consent procedure, respondents will be asked whether they allow audio recording of the interview. Recording will not begin before participants have had the opportunity to ask for any clarification and provide consent. Participants will be asked to again confirm their consent when recording begins. Participants who do not allow audio recording may still participate in the interview. In these cases, Westat will take notes that are more detailed than when relying on the audio recording.

No participant's identifiable information such as name will be included in the interview notes. All interview materials will be stored on a secure network drive, which will only be accessible to individuals granted access to work on the project. Interview notes will be zipped electronically and password-protected for email or secure file transfer delivery. Prior to forwarding any data to FDA, Westat will destroy all names and contact information of participants to protect their personal identity. Additionally, the interview notes and interpretive report delivered to FDA after message testing will omit all information that could be used to identify respondents.

All electronic data storage media that contain confidential, private, or proprietary information will be maintained within secure areas. Data collected in hard copy will be kept in locked cabinets when not in use.

FDA's Institutional Review Board (IRB) reviewed this study and determined it is exempt from the requirements of 45 CFR §46.101b(2).

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

For this project, Plaza Research will provide $50 incentives to participants at the end of each 45-minute interview in the form of a check.

Plaza Research uses a "by-invitation-only" recruitment methodology and incentivizes panelists for any participation to maintain a quality filled panel. Panel members do not volunteer their time. Plaza's incentive scale is based on set time increments and is applied equally across all study topics, sponsors, and data collection modes. The table below details the previous incentives approved by OMB for this series of rapid message tests.

Project #	Communication Tested	Interview Length/Incentive	OMB approval date
1	Clinical Trials Brochure	45 min/$50	August 4, 2017
2	Caregiver Tipsheet	30 min/$35	September 26, 2017
3	Public Service Announcement Video about Generic Drugs	30 min/$35	October 25, 2017
4	Opioid Analgesics Patient Counseling Guide	45 min/$50	November 27, 2017
5	Vaccines and Seniors Brochure	30 min/$35	May 10, 2018
6	Public Service Announcements about Safe Disposal of Opioids	30 min/$35	July 26, 2018
7	Nicotine Dialogue Campaign Branding	30 min/$35	August 23, 2018
8	Testosterone Medication Guide	45 min/$50	October 12, 2018
9	Asthma Fact Sheet	30 min/$35	February 12, 2019
10	Transmucosal Immediate Release Fentanyl Risk Evaluation Mitigation Strategy Program Patient-Prescriber Agreement Form	45 min/$50	April 4, 2019
11	BeSafeRx Campaign Messages	45 min/$50	May 17, 2019
12	Safe Drug Disposal Notecard	30 min/$35	June 28, 2019
13	Medical Countermeasures	45 min/$50	September 10, 2019
14	Warnings on Opioid Packaging	30 min/$35	October 22, 2019
15	Messages About Cannabidiol (CBD)	30 min/$35	January 2, 2020
16	FDA's Purple Book Website	45 min/$50	January 16, 2020
17	Storyboards about Safe Disposal of Opioids and Other Medicines	45 min/$50	April 14, 2020
18	Medication Guide Template for Buprenorphine Products	30 min/$35	May 13, 2020
19	Retest Warnings on Opioid Packaging	30 min/$35	June 19, 2020
20	Drug Safety Communications About Misuse and Abuse of Over-the-Counter Medications	45 min/$50	December 9, 2020

8. **Questions of a Sensitive Nature**

The screener and interview guide will include potentially sensitive questions on misuse and abuse of OTCs and prescription medicines. These questions relate directly to key outcomes of the study. These questions will provide context on familiarity with and previous experience with misuse and abuse of legal substances.

Respondents will be told that they may skip any question that they do not want to answer or may stop participating at any time.

9. **Description of Statistical Methods**

We do not plan to use formal statistical methods in this study but rather qualitative analysis methods. Our analysis approach is based on the Framework method, as described in Spencer et al (2003). Framework is a matrix-based approach to data management, which facilitates both case and theme based analysis. The Framework method allows for data reduction through summarization and synthesis yet retains links to original data, in this case the interview notes. We will use the qualitative analysis software NVivo, which has included a Framework functionality since 2011. The software will allow us import interview notes, create links between the notes and the Framework matrices, and develop new queries or matrices as needed.

The Framework method will allow us to recognize patterns within the data. Findings will be supported with verbatim participant quotes and grounded in accepted principles of health communications.

Bibliography

Guest, G., Bunce, A., & Johnson, L. (2006). How many interviews are enough? An experiment with data saturation and variability. Field methods, 18(1), 59-82.

McNeely, J., Halkins, P., Horton, A., Khan, R., Gourevitch, M. (2014). How patients understand the term ‘nonmedical use’ of prescription drugs: Insights from qualitative interviews. Substance Abuse, 35(1), 12-20.

Spencer, L., Ritchie, J., & O'Connor, W. (2003). Analysis practices, principles and processes. In *Qualitative research practice.* London: Sage Publications.

BURDEN HOUR COMPUTATION *(Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours):*

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Screener	750	3	38
Interviews	9	45	7
Total			45

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