## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–0862]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; The Real Cost Campaign Outcomes Evaluation Study: Cohort 3

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by March 9, 2023.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''The Real Cost Campaign Outcomes Evaluation Study: Cohort 3.'' Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### The Real Cost Campaign Outcomes Evaluation Study: Cohort 3

*OMB Control Number 0910—NEW*

This information collection supports the development and implementation of FDA's public education campaign related to tobacco use. To reduce the public health burden of tobacco use in the United States and educate the public—especially young people—about the dangers of tobacco use, the FDA Center for Tobacco Products (CTP) is developing and implementing multiple public education campaigns.

FDA launched ''The Real Cost'' in February 2014, seeking to reduce tobacco use among at-risk youth ages 12–17 in the United States who are open to smoking cigarettes and/or using electronic nicotine delivery systems (ENDS) products, or have already experimented with cigarettes and/or ENDS products. Complementary evaluation studies, including the ''Evaluation of FDA's Public Education Campaign on Teen Tobacco (ExPECTT),'' were designed and implemented to measure awareness of and exposure to ''The Real Cost'' paid media campaign among youth ages 12–17 in targeted areas of the United States.

The first cohort (ExPECTT: Cohort 1) assessed the campaign's impact on outcome variables of interest from November 2013 to November 2016. The second cohort (ExPECTT: Cohort 2) has been assessing the campaign's impact on outcome variables of interest from June 2018 and will run through August 2022. To continue assessing the impact of ''The Real Cost'' campaign, FDA will implement The Real Cost Campaign Outcomes Evaluation Study: Cohort 3. The study will consist of four waves of data collection, including the baseline survey and three follow-up (FU) surveys. Online surveys with youth ages 11–20 will be conducted at baseline.

Online surveys of youth will be conducted in the United States to measure the effectiveness of FDA's ''The Real Cost'' campaign. The purpose of FDA's The Real Cost Campaign Outcomes Evaluation Study: Cohort 3 is to evaluate whether changes in key outcomes can be attributed to exposure to the campaign. The strength of the attribution is determined by the ability of the evaluation approach to rule out alternative explanations for observed changes in key outcomes. To improve attribution, we intend to measure self-reported campaign exposure to media advertising, which among many things, will enable FDA to assess its relationship with market-level delivery.

The goal of The Real Cost Campaign Outcomes Evaluation Study: Cohort 3 is to determine whether future waves of ''The Real Cost'' public education campaign will influence key outcomes including:

- Awareness of campaign messages (self-reported exposure)
- Specific beliefs targeted by messages (message-targeted beliefs)
- Psychosocial predictors or precursors of tobacco use behavior
  - Health and addiction risk perceptions
  - Perceived loss of control or threat to freedom expected from tobacco use
  - Anticipated guilt, shame, and regret from tobacco use
  - Tobacco use susceptibility
  - Intention or willingness to use tobacco
  - Intention to quit and/or reduce daily consumption

In support of the provisions of the Tobacco Control Act (Pub. L. 111–31) that require FDA to protect the public health and to reduce tobacco use by minors, FDA requests OMB approval to collect information to evaluate CTP's public education campaign ''The Real Cost'' through the Evaluation Study: Cohort 3.

In the **Federal Register** of July 26, 2022 (87 FR 44409), FDA published a 60-day notice requesting public comment on the proposed collection of information. One PRA related comment was received.

(Comment) The commentor does not support this data collection and expressed concerns with collecting data from those who identify as LGBTQ+. The rational for not collecting these data is because those who identify as LGBTQ+ are at risk for privacy and security concerns by asking them to report their sexual orientation or gender identification. The commentor believes this type of questioning is invasive and may expose LGBTQ+ members to further bias and discrimination. Further, the commentor believes that FDA's proposal to target LGBTQ+ youth aged 11–17 is concerning as youth can be particularly vulnerable to exploitation for two reasons: (1) their minds are still developing, and (2) ''function creep'' occurs when data is collected for one reason and can then be utilized for other, non-intended purposes.

(Response) FDA appreciates the comment in response to the 60-day notice. We provide more information below about why this is an important opportunity to support LGBTQ+ youth populations and how FDA is proposing to carry out this collection of information in a manner that minimizes risks, while building credible and useful evidence about LGBTQ+ youth populations. This data will be used to inform tobacco public education campaigns that aim to reduce tobacco use disparities, including among LGBTQ+ populations. Recent data from the 2021 National Youth Tobacco Survey demonstrates that teens who are sexual or gender minorities have higher rates of cigarette and e-cigarette use compared to heterosexual teens. For

example, 6 percent of heterosexual teens reported ever experimenting with cigarettes, compared to 10.9 percent of gay or lesbian teens, 15.6 percent of bisexual male teens, 14 percent of bisexual female teens, and 11.2 percent of teens who are transgender. Furthermore, 17.9 percent of heterosexual teens reported ever using e-cigarettes, compared to 27.3 percent of bisexual male teens, 29.6 percent of bisexual female teens, and 30.7 percent of teens who are transgender. This is credible evidence as to why LGBTQ+ youth are priority populations when it comes to minimizing health disparities.

The cited negative impact raised by the commentor, in which data collected are misused to the detriment of LGBTQ+ youth, is mitigated by the extensive, specific, and efficacious measures and practices put in place by FDA and its contractors to secure data privacy and avoid individual harm. This is not a broad data collection effort but rather data collection limited in nature solely for the purpose of collecting data to answer a circumscribed set of questions that will support FDA's mission of protecting and promoting public health which includes LGBTQ+ youth populations. To address the privacy concerns mentioned in the comment, FDA has included a document in the docket which details the privacy protections for this study.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Respondent/Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Parent Recruitment Study Materials—Main: Baseline & Follow-up 2 Replenishment. | 545,000 | 1 | 545,000 | 0.17 (10 minutes) | 92,650 |
| Parent Screener—Main: Baseline & Follow-up 2 Replenishment | 272,500 | 1 | 272,500 | 0.08 (5 minutes) | 21,800 |
| Household Roster—Main: Baseline & Follow-up 2 Replenishment | 5,500 | 1 | 5,500 | 0.08 (5 minutes) | 440 |
| CATI Screener—Main: Baseline & Follow-up 2 Replenishment | 2,000 | 1 | 2,000 | 0.08 (5 minutes) | 160 |
| Parent Permission—Main: Baseline & Follow-up 1,2,3 | 21,600 | 1 | 21,600 | 0.08 (5 minutes) | 1,728 |
| Youth Assent—Main: Baseline & Follow-up 1,2,3 | 21,600 | 1 | 21,600 | 0.08 (5 minutes) | 1,728 |
| Youth Survey—Main: Baseline & Follow-up 1,2,3 | 21,600 | 1 | 21,600 | 0.50 (30 minutes) | 10,800 |
| Youth Screener—Supplemental | 5,000 | 1 | 5,000 | 0.08 (5 minutes) | 400 |
| Youth Assent—Supplemental: Baseline & Follow-up 1,2,3 | 4,428 | 1 | 4,428 | 0.08 (5 minutes) | 354 |
| Youth Survey—Supplemental: Baseline & Follow-up 1,2,3 | 4,428 | 1 | 4,428 | 0.50 (30 minutes) | 2,214 |
| Total | | | | | 132,274 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

**Main Data Collection**

The main data collection will include a baseline survey and three FU surveys. The recruitment sample for the main data collection is youth ages 11–17. We intend to replenish the longitudinal sample at FU2 to obtain 6,000 youth respondents to maintain at least 4,800 respondents at each wave. We expect the screening process to yield a 100:1 ratio of eligible responding households. We estimate that we will mail 400,000 recruitment/study material packages (10 minutes per response) in order to receive at least 200,000 completed screeners (5 minutes per response) by adults within households. Households completing the screener by mail will be contacted to complete a computer-assisted telephone interview (CATI) where an interviewer will determine eligibility and obtain parental permission (5 minutes per response). For households identified as eligible for the study during the screening process (*i.e.,* the presence of 1 or more youth ages 11 to 17), we will ask the parent/guardian to list all eligible youth in their households for study selection, a process called rostering (5 minutes per response). We estimate from the 200,000 completed screeners, we will recruit 6,000 eligible youth from the 4,000 eligible households.

**Baseline**

At baseline, we plan to collect data from approximately 6,000 youth respondents from the 4,000 eligible households identified through screening. More than one eligible youth per household may be recruited for the study. These 6,000 youth respondents are estimated to provide baseline assent (5 minutes per response) and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study. We estimate that we will lose approximately 20 percent of the original baseline sample at each FU wave.

**Follow-Up 1**

We estimate that we will retain 80 percent of the sample from baseline and collect data from 4,800 respondents (5 minutes per response) at FU1. These 4,800 youth respondents are estimated to provide assent (5 minutes per response) for FU1 and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study. We do not intend to replenish the sample at FU1.

**Follow-Up 2**

We estimate that we will retain 80 percent of the sample from FU1 resulting in 3,840 respondents at FU2. To replenish the longitudinal sample at FU2, we will send additional ''baseline'' screeners to new households. We intend to send recruitment/study material packages to an additional 145,000 households (10 minutes per response) to receive an estimated 72,500 completed screeners (5 minutes per response). For households identified as eligible for the study during the screening process (*i.e.,* the presence of 1 or more youth ages 11 to 17), we will ask the parent/guardian to list all eligible youth in their households for study selection, a process called rostering (5 minutes per response). Households completing the screener by mail will be contacted to complete a CATI where an interviewer will determine eligibility and obtain parental permission (5 minutes per response). From these completed screeners, we estimate that we will obtain data from an additional 2,160 youth within approximately 1,500 households. Replenishing the sample will allow us to obtain 6,000 youth respondents at FU2 (3,840 from the original sample, and 2,160 from the replenishment sample) and maintain a minimum study sample of 4,800 respondent at all study waves. These 6,000 youth respondents are estimated

to provide assent (5 minutes per response) for FU2 and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study.

**Follow-Up 3**

We estimate that we will retain 80 percent of the sample from FU2 and collect data from 4,800 respondents at FU3. We do not intend to replenish the sample at FU3. These 4,800 youth respondents are estimated to provide assent (5 minutes per response) for FU2 and complete the survey (30 minutes per response). For these youth respondents, we will ask the parent/guardian to provide permission (5 minutes per response) for the youth to participate in the study.

**Supplemental Data Collection**

In addition to the main data collection, we intend to collect data from subpopulations shown to be at higher risk of initiating use of cigarettes and ENDS products, such as youth who identify as LGBTQ+ and youth who have a mental health disorder. Data collection will consist of online self-administered surveys of participants recruited through social media advertisements. The recruitment sample for this data collection will be youth ages 14 to 20 who meet the subpopulation criteria. We intend to collect data at baseline from 1,500 respondents. We anticipate that we will need to screen 5,000 respondents (5 minutes per response) to obtain a baseline sample of 1,500 respondents who meet the subpopulation criteria. At baseline, we plan to collect data from approximately 1,500 respondents identified as eligible through screening. These 1,500 youth respondents are estimated to provide assent (5 minutes per response) and complete the survey (30 minutes per response). We estimate that we will lose approximately 20 percent of the original baseline sample at each FU wave; therefore, estimating 1,200 respondents at FU1, 960 respondents at FU2, and 768 respondents at FU3. For the FU samples, youth will provide assent (5 minutes per response) and complete the survey (30 minutes per response).

We made several minor edits from the 60-day **Federal Register** notice to the 30-day **Federal Register** notice. These edits consisted of (a) minor revisions for clarity (*e.g.,* indicating that self-report exposure is a measures of awareness rather than a unique outcome); (b) removing text alluding to using multiple methods to understand the campaign impact (because the proposed study is just one method); and (c) removing bullets on two outcomes related to perceived norms of tobacco use, as the ads that will be on air at the time of data collection are not attempting to change those particular outcomes so they are not relevant to assess in the study.

Dated: February 1, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–0008]**

### Advisory Committee; Cellular, Tissue, and Gene Therapies Advisory Committee; Renewal

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of Federal advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the renewal of the Cellular, Tissue, and Gene Therapies Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Cellular, Tissue, and Gene Therapies Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 28, 2024, expiration date.

**DATES:** Authority for the Cellular, Tissue, and Gene Therapies Advisory Committee will expire on October 28, 2024, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Christina Vert, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1244, Silver Spring, MD 20993–0002, 240–402–8054, *Christina.Vert@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Cellular, Tissue, and Gene Therapies Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products which are intended for transplantation, implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair, or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program that provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 13 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of cellular therapies, tissue transplantation, gene transfer therapies and xenotransplantation (biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine, and various medical specialties, including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics). Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives, or Ex-Officio members. Federal members will serve as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to