

Supporting Statement A

2019 LUNG INJURY RESPONSE UNDERSTANDING VAPING PRACTICES IN THE UNITED STATES

Request for OMB approval of a New Emergency Information Collection

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- **Goal of the study:** We propose conducting a formative study to collect data from individuals who vape/dab tetrahydrocannabinol (THC) but who have not developed lung injury in order to compare characteristics with those who have developed the injury to help further the ongoing public health investigation. The goals of this study are to:
 - (1) Collect data about product types, brands, devices, and frequency of use from a convenience sample of individuals who report vaping THC-containing products but who have not developed e-cigarette, or vaping, product use associated lung injury (EVALI)
 - (2) Assess the vaping characteristics/behaviors of non-cases (those who vape but have not developed EVALI) to those of EVALI cases
- **Intended use of the resulting data:** The results of this information collection will inform CDC’s ongoing public health response to the multi-state lung injury outbreak by helping to narrow the list of products, substances, and risk factors requiring further public health action, epidemiological and clinical analyses, and laboratory testing.
- **Methods to be used to collect data:** An opt-in internet panel survey of approximately 5,250 individuals who report vaping THC-containing products within the last 3 months who have not developed EVALI. This method allows for the rapid collection of information on a timely issue.
- **The subpopulation to be studied:** A geographically diverse convenience sample of individuals who are vaping the same or similar products at the same or similar frequency but have not developed EVALI.
- **How data will be analyzed:** We will compare the frequency of usage characteristics between the survey sample (controls who have not developed EVALI) and EVALI cases.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control (NCIPC), requests an emergency 90-day approval for a New Information Collection, “2019 Lung Injury Response Understanding Vaping Practices in The United States.”

In early August 2019, initial cases of e-cigarette, or vaping, product use associated lung injury (EVALI) were reported to CDC. On August 16, 2019, the Wisconsin and Illinois departments of health submitted a request for CDC Epi-aid assistance to investigate an outbreak of lung injury associated with e-cigarette use, vaping, or dabbing. The investigation rapidly expanded to become a multi-state, centrally organized investigation with approval for multi-state data collection issued by the Office of Management and Budget on August 29, 2019 (OMB# 0920-1011, exp. 01/31/2020). On September 16, 2019, CDC activated its Emergency Operations Center (EOC) to enhance the agency’s response to this emergency. A multi-state centrally coordinated response for EVALI was established at CDC to assist each state/local/territory jurisdiction in making rapid, practical decisions for actions to prevent and control this public health problem. As of November 13, 2019, 2,172 EVALI cases have been reported to CDC from 49 states, the District of Columbia, the US Virgin Islands, and Puerto Rico, with 42 deaths among these cases.¹

Based on reports from several states,² patients have experienced respiratory symptoms (e.g., cough, shortness of breath, or chest pain), and some have also experienced gastrointestinal symptoms (e.g., nausea, vomiting, or diarrhea) or non-specific constitutional symptoms (fatigue, fever, or weight loss). Symptoms typically develop over a period of days but sometimes can manifest over several weeks. Gastrointestinal symptoms sometimes have preceded respiratory symptoms. Fever, tachycardia, and elevated white blood cell count have been reported in the absence of an identifiable infectious disease.

To date, all EVALI patients have reported a history of using e-cigarette, or vaping, products. The latest national and state findings suggest products containing THC, particularly from informal sources like friends, or family, or in-person or online dealers, are linked to most of the cases and play a major role in the outbreak. In addition, vitamin E has been identified as a chemical of concern among people with e-cigarette, or vaping, product use associated lung injury (EVALI).³ However, while it appears that vitamin E acetate is associated with EVALI, evidence is not yet sufficient to rule out contribution of other chemicals of concern to EVALI. Many different substances and product sources are still under investigation, and it may be that there is more than one cause of this outbreak. Additional compounds or ingredients have not been identified but CDC has not ruled out that other ingredients or compounds may be involved. Overall, there are still many unanswered questions about specific products, sources, and use behaviors. In fact, many different substances and product sources are still under investigation. Most case patients report a history of use of THC containing products, particularly those obtained off the street or

¹ Centers for Disease Control and Prevention. (2019). “Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products Accessed November 14, 2019. https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#latest-outbreak-information.

² Layden JE, Ghinai I, Pray I, Kimball A, Layer M, Tenforde M, et al. (2019). “Pulmonary Illness Related to E-Cigarette Use in Illinois and Wisconsin — Preliminary Report.” *New England Journal of Medicine* DOI: 10.1056/NEJMoa1911614.

³ Blount BC, Karwowski MT, Morel-Espinosa M, Rees J, Sosnoff C, Cowan E, et al. (2019). “Evaluation of Bronchoalveolar Lavage Fluid from Patients in an Outbreak of E-cigarette, or Vaping, Product Use–Associated Lung Injury — 10 States, August–October 2019.” *MMWR* 68(45): 1040-1041.

from other informal sources (e.g. friends, family members, illicit dealers).⁴ At present, there is very little data on which to compare EVALI cases to individuals who are vaping the same products at the same frequency but have not developed EVALI (i.e. “controls”). Comparing cases to people who vape THC but have not developed EVALI in a timely way is essential for narrowing the list of products, substances, and risk factors requiring further public health investigation and action (e.g., prioritizing samples for laboratory testing and epidemiological surveillance). Further, there are insufficient data for guiding the selection of controls for a rigorous case control study, due to a lack of uniformity in demographic characteristics and product brands and types among cases.

To this end, CDC-NCIPC is proposing this information collection to identify the vaping-related characteristics and behaviors of those who have recently vaped THC-containing products but not developed EVALI and compare these vaping-related characteristics of those who have developed EVALI. NCIPC is seeking approval from OMB to conduct a survey via an opt-in internet panel and compare these data with data from EVALI case patients. A sample of respondents who are already part of the opt-in panel will be invited to participate in this survey to describe their vaping history and experiences (**Attachment 2**). The results of this study will allow us to better target our future laboratory, clinical, and epidemiological analyses.

The proposed information collection is authorized by the Public Health Services Act (PHS Act) which provides the legislative means for states to advance public health across the lifespan and to reduce health disparities. Section 301 (a) of the PHS Act, 42 U.S.C. 241 (a), authorizes grants to aid “other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the cause, diagnosis, treatment, control and prevention of physical and mental diseases and impairments of man” (**Attachment 1**).

2. Purpose and Use of Information Collection

The purposes of this study are to (1) Collect data about product types, brands, devices, and frequency of use from a sample of individuals who report vaping tetrahydrocannabinol (THC)-containing products but who have not EVALI and (2) to compare the vaping characteristics/behaviors of non-cases (those who vape but have not developed EVALI) to those of EVALI cases. The survey contains a series of up to 34 questions that assess the respondents’: 1) types of THC substance(s) used in vaping products 2) product sources 3) specific “brands” used 4) devices/products used 5) other substances used or vaped and 6) frequency of use in the past three months. A full description of what we know, key questions asked, secondary questions asked, and implications for responses for each of the six topic areas can be found in **Attachment 3**.

The data collected will be used to identify substances used, product types, “brands,” devices, and frequency of use (collectively referred to as use characteristics) from a geographically diverse convenience sample of individuals who report vaping THC-containing products but have not developed EVALI. Comparing the frequencies of these use characteristics between the convenience sample (controls) and EVALI cases will allow us to (1) prioritize follow up on hypotheses about potential risk factors for or causes of the outbreak and (2) refine, target, and prioritize additional information gathering efforts, e.g. epidemiological analyses, laboratory testing, and analysis of pathological specimens.

⁴ Moritz ED, Zapata LB, Lekiachvili A, Glidden E, Annor FB, Werner AK, et al. (2019). “Update: Characteristics of Patients in a National Outbreak of E-cigarette, or Vaping, Product Use-Associated Lung Injuries – United States, October 2019. *MMWR* 68(43);985-989.

This request is to obtain OMB approval for collection of data through an online survey of individuals registered with the opt-in internet panel survey YouGov.⁵ YouGov specializes in market research and opinion polling through online methods. The company's methodology involves obtaining responses from an invited group of Internet users, and then weighting these responses in line with demographic information (note: CDC will only use unweighted data). YouGov's US internet panel has over 2 million regionally and socioeconomically diverse respondents.⁶ The panel is pre-screened allowing for a quick survey turn-around. CDC identified the YouGov opt-in internet panel survey as the preferred contractor based on available resources and procurement mechanisms available to CDC as well as prior experience with the contractor being able to conduct surveys in a geographically diverse set of states.

The proposed approach leverages the benefits of an opt-in internet panel survey to rapidly collect specific information on a demographically and geographically diverse convenience sample of individuals who report vaping THC-containing products but have not developed EVALI. Because such a sampling frame is not nationally representative and not suitable for generalizing about populations, only un-weighted data will be obtained from the opt-in internet panel survey contractor and only unweighted and aggregate results will be shared with partners or publicly. The time constraints associated with epidemic investigation, the available funding, and the difficulty in collecting data about illicit activities (even in states where cannabis markets are regulated) prevent us from being able to measure potential regional and/or state variation in supply chains and/or vaping behaviors.

Therefore, our goal will be to recruit as many people as possible who meet the inclusion criteria in Table 16B below. We will recruit individuals that live in a geographically diverse set of states that represent a mix of states with higher and lower counts of EVALI cases, as well as states that have legal cannabis markets and those that do not. CDC has identified the following states representing a geographically diverse area with a mix of states with and without regulatory cannabis markets. The states we are proposing are WA, CA, UT, CO, ND, TX, IL, WI, MN, TN, NC, PA, NY, NJ, MA.

The inclusion criteria for respondents is: 1) age 18 years or older; 2) no diagnosis of probable or confirmed EVALI in the past year; 3) report vaping or dabbing of THC at least five times in the preceding three months; and 4) reside in one of the selected states. These requirements are intended to identify the specific comparison population of interest. We have intentionally chosen to use the terms vaping/dabbing to isolate THC use over nicotine use via e-cigarettes; this is based on conversations with states involved in the response and those that oversee legal cannabis markets in their state and is intended to use language that is likely to resonate with the target population of interest. The survey instrument was developed: 1) consistent with the current EVALI case interview form; 2) to provide data for use in prioritizing additional epidemiological, laboratory, and pathological investigations in the context of understanding the epidemic of EVALI.

3. Use of Improved Information Technology and Burden Reduction

Information on participants will be collected by online survey. The computer-based survey to collect and process data reduce respondent burden and make data processing reporting timelier and more efficient.

⁵ YouGov PLC. (2018). "YouGov is an international research data and analytics group." Accessed on November 7, 2019. <https://corporate.yougov.com/about/>

⁶ YouGov PLC. (2018). "Our Panel." Accessed on November 7, 2019. <https://today.yougov.com/about/about-the-yougov-panel/>.

The programmed survey automatically skips questions based on the individual's responses. This automation saves administration time, improves data quality, and reduces burden by removing the need for the respondent to manually navigate skip patterns, which would be required if the survey was administered by paper and pencil. It also reduces burden because participants only need to read the survey questions that are relevant to them. Time and cost for data processing is reduced because the data is collected and entered at the same time and is quickly available for analysis.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of similar data collection efforts regarding this particular type of emergency. There are very little data on which to compare EVALI cases to individuals who are vaping the same products at the same frequency but have not developed EVALI. Comparing cases to people who vape but have not developed EVALI in a timely way is very important for narrowing the list of products, substances, and risk factors requiring further public health action (e.g., continuing to refine communication messages) and additional studies (e.g., prioritizing samples for laboratory testing).

However, there are other federal collections that do collect limited data regarding smoking and vaping behaviors. The CDC conducts several national surveys that contain vaping-related questions. The CDC's Youth Risk Behavior Survey (YRBS – OMB# 0920-0493, exp. 11/30/2019) continually collects data from a large sample of high school students. Pertinent questions include how many days in the past 30 days did the student use an electronic vapor product and from where they usually obtained their vapor products. The CDC's Behavioral Risk Factor Surveillance System (BRFSS – OMB #0920-1061, exp. 3/31/2021) is an on-going telephone survey of U.S. residents of all 50 states. BRFSS asks how often the respondents use e-cigarettes or other electronic vaping products (for nicotine use) and whether they use marijuana by vaping it. However, the marijuana questions are an optional module and only a handful of states are currently using it. The CDC's National Youth Tobacco Survey (NYTS; OMB# 0920-0621, exp. 04/30/2021) assesses 6th through 12th grade students' use of tobacco products in a variety of forms as well as their knowledge of and attitudes toward tobacco. It asks youth if they have ever been curious about using tobacco products, age at first use, number of days of lifetime and past 30 days use, where they bought/procured e-cigarettes in the last 30 days, and whether they have ever used marijuana in an e-cigarette. In the recent past, CDC also fielded a National Adult Tobacco Survey (NATS; OMB# 0920-0828, exp. 07/31/2015), but it has not been conducted since 2013-2014. The CDC's National Health Interview Survey (NHIS; OMB# 0920-0214; exp. 12/31/2020) is an in-person, household survey that asks adult respondents how frequently they use e-cigarettes and how many of the past 30-days they have used e-cigarettes. Starting in 2019, these vaping questions will specifically exclude marijuana and focus solely on nicotine or other products. The CDC's National Health and Nutrition Examination Survey (NHANES; OMB# 0920-0950, exp. 11/30/2021) is also a household interview study and asks adults in how many of the past 30-days they have used e-cigarettes. This question specifically focuses on e-cigarettes use for vaping nicotine. Finally, the CDC has partnered with the World Health Organization to field the Global Youth Tobacco Survey (GYTS). The GYTS is a school-based survey that collects data on students ages 13-15 years. This survey asks youth if they have ever heard of electronic cigarettes, how many days in the past 30 they have used e-cigarettes, and how many days in their lifetime they have used e-cigarettes. Again, this question focuses on use of e-cigarettes for vaping nicotine specifically.

Outside of CDC, the National Survey on Drug Use and Health (NSDUH - OMB# 0930-0110, exp. 10/31/2022), administered by Substance Abuse and Mental Health Services Administration (SAMHSA)

collects and reports data on substance use incidence and prevalence and mental health statistics for the civilian, non-institutionalized population aged 12 or older in the U.S. as well as for each state. NSDUH accurately estimates drug use and related mental health measures among the aging drug use population. Although NSDUH does capture information on use of tobacco and marijuana, as of the recently released 2018 data, no questions related to e-cigarette, or vaping, of these substances were included. Monitoring the Future, an NIH-funded study of 8th, 10th, and 12th graders does include a limited number of questions on use of e-cigarette, or vaping, of nicotine and marijuana products.

The YRBS, BRFSS, NHANES, NYTS, and NSDUH also ask specific questions about marijuana use (e.g. age at first use, frequency of use, etc.). Only the BRFSS and NYTS inquire as to whether the marijuana was consumed via vaping or e-cigarette. However, the aims of all of these surveys are different from the aim of the proposed information collection. The YRBS, BRFSS, NHANES, NYTS, NSDUH, and GYTS all aim to estimate the prevalence of tobacco use, marijuana use, and/or certain limited vaping behaviors. None of these national surveys include questions about the newly discovered lung injury associated with vaping or e-cigarette use, nor the specific brands or devices used. We are confident that no effort has been undertaken by other federal agencies which closely matches the one we are proposing because the data that they currently collect do not allow for a comparison of EVALI cases to individuals who are vaping the same products at the same frequency but have not developed EVALI. For this reason, a new information collection is needed.

5. Impact on Small Businesses or Other Small Entities

The collection of information does not primarily involve small entities.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. Without collecting these data, CDC will not have adequate information to understand if and how the behaviors among EVALI cases and among individuals who are vaping the same products at the same frequency but have not developed EVALI differ. This information collection will be the first to enable a comparison between these two groups which will facilitate further targeting of laboratory, epidemiological, and clinical analyses and studies as part of the ongoing lung injury response.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived. However, a 60-day *Federal Register* notice will be submitted to make the public aware of this investigation. Any public comments will be used for future studies.

B. The efforts to consult outside the agency are outlined below:

CDC has been working closely with Departments of Health in 49 states, Washington DC, the US Virgin Islands, and Puerto Rico to monitor EVALI cases.

Additionally, CDC staff from the National Center for Injury Prevention and Control and the CDC's Office on Smoking and Health reviewed the survey and protocol and provided feedback on the electronic versions of the instruments during conference calls and via email, as did representatives from state health departments involved in the lung injury response.

9. Explanation of Any Payment or Gift to Respondents

Upon completion of a particular survey, the standard protocol for YouGov is to reward their panelists with points which can later be redeemed for rewards. A typical survey rewards a panelist with 1,000 points, which is the equivalent of \$1. Once a certain number of points are accumulated, the panelist can trade in their points for a gift card for brands/vendors such as Amazon, Best Buy, Target and Gamestop. For this study YouGov will offer panelists 2,000 points (\$2 equivalent) for survey completion due to the emergency nature of the collection. Although we recognize that providing a survey incentive is not a common practice among government surveys, the emergency nature of this collection and the fast turn-around for recruiting participants willing to answer potentially sensitive vaping questions is driving us to provide these nominal incentives.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by the CDC NCIPC's Information Systems Security Officer, who has determined that the Privacy Act does not apply because CDC will not have access to or receive any personally identifiable information (PII) about participants. The Privacy Impact Assessment (PIA) is attached (**Attachment 4**). YouGov is an online panel that allows individuals to voluntarily respond to surveys of their choosing in exchange for a nominal incentive. The PII data is already collected and managed by YouGov. CDC will only receive de-identified data. Respondents will be assigned a study ID for use on data collection instruments, and all data files shared with CDC will be de-identified to maintain the privacy of those who participated in the study. The only demographic information we will receive from YouGov is the respondents' sex, age, race/ethnicity, and state in which they reside. This is the same information we have received from the EVALI case reports and are important for comparison purposes. None of these pieces of data allow for identification of individual respondents. No personal health information will be collected or maintained.

Participation in the survey will be voluntary for all respondents. Potential participants will be emailed information about the survey and what is required for participation (**Attachment 5**). PII, such as the name of the respondent and his/her contact information will not be stored in the initial data files at any time. Unique identifiers will be assigned to each case in the data files as data are collected. Survey data will be stored by YouGov in secure servers. YouGov maintains all respondent profile information on a separate server from survey responses/attitudinal data. Upon contract termination and per the terms of the agreement, YouGov will destroy all data related to this information collection at the completion of the project. Data files will be delivered to CDC NCIPC using a secure file transfer protocol (SFTP) site. All data collected from the survey will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. CDC will retain and destroy records in accordance with the applicable CDC Records Control Schedule.

All respondents will be told during the consent process (**Attachment 6**) that the data they provide will be treated in a secure manner to the extent allowed by law. They also will be informed that participation is voluntary, that they may refuse to answer any question, and can stop at any time without risk. In addition, names of participants in any component of the study will not be provided to the federal

government. Instead, a unique ID will be assigned to each participant. Participants will be made aware that the CDC may report the results of the survey in aggregate. They will be informed that their names will not be used with individual responses. Only approved members of the project team will have access to the data collected through the survey for the purposes of analysis and reporting. YouGov also provides their panelists with an assurance of privacy and confidentiality. More information on their policies can be found [here](#).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

The protocols and tools used to conduct this information collection request have been reviewed and approved by NCIPC's Human Subjects Advisor, who determined that this data collection does not meet the definition of research under 45 CFR 46.102(d). IRB review is not required (**Attachment 7**).

Justification for Sensitive Questions

In this information collection, potentially sensitive questions will be asked. Specifically, respondents will be asked about their use of marijuana and THC-containing substances. Although marijuana is legal for adult recreational and/or medical use in some states, it is still considered an illicit Schedule I controlled substance by the federal government under the Controlled Substances Act. The reported source of the THC-containing product is also sensitive in nature. In order to protect the privacy of respondents and ensure that information will not be disclosed, CDC has received an Assurance of Confidentiality (AoC) under Section 308(d) of the Public Health Service Act for the protection of identifiable and potentially identifiable information on the outbreak of lung injury associated with e-cigarette product use, or vaping (i.e., the 2019 Lung Injury Response) collected by CDC in collaboration with the U.S. Food and Drug Administration (FDA), state and local health departments, Tribal and Territorial Entities, and other clinical and public health partners (**Attachment 8**). CDC is requesting an amendment to the AoC in order to cover the current information collection.

In order to ease the panelists into the THC-related questions, we will first ask them a series of questions related to lung injury and their use of nicotine-containing e-cigarette products. These questions are both important for our analytic purposes (i.e. we will examine whether cases and non-cases vary based on nicotine-vaping behaviors) as well as acting as a lead-in to the more sensitive questions related to THC. We will explain to study participants that all questions are asked for analytic purposes only. Participants may decline to respond to any question, and they will still be able to participate in the survey. The informed consent for the survey (**Attachment 6**) explains that participants can refrain from answering any questions. All questions are voluntary in nature. There will be no negative consequences to any respondent, should they choose not to answer one or all of the questions. In the informed consent, we will inform all study participants that all data collected will be treated in a secure manner. The inclusion of all sensitive survey questions is critical for our purposes, though. The latest national data indicate that THC-containing products, particularly those obtained from informal or illicit sources play a major role in the outbreak. In order to determine if those that vape THC-containing products but do not develop EVALI have the same characteristics of EVALI cases, it is necessary to ask about the non-cases' use of THC products.

12. Estimates of Annualized Burden Hours and Costs

YouGov panelists will be invited by email to participate in the EVALI survey (**Attachment 5**). Our desired sub-population for the survey contains individuals who are vaping the same products at the same frequency but have not developed EVALI. All panelists who opt-in to the survey will first be screened by asking whether or not they are 18 years or older and live in one of our 15 selected states. If they answer no to either of those questions, they will not be allowed to continue the rest of the survey. If they answer yes to both the age and location question, the respondents will then be asked a question related to their use of nicotine-containing e-cigarettes in the past 3 months. This is followed by a question on whether they have been diagnosed with lung injury in the past year related to use of e-cigarette, or vaping, products. If they answer no to this question, they are then asked the final screening question, “In the past 3 months, have you vaped or dabbled marijuana or THC (the psychoactive compound in marijuana) at least five times? This includes items you’ve purchased at a store, bought off the street, or that were given to you by someone?” If they answer “no” to this question, they will not be asked any follow-up questions and will not be included as part of our final sample. The survey was designed this way in order to not place the potentially sensitive THC questions at the beginning. However, this does impact the number of respondents who answer any questions in order to roster our target sample size and therefore increases the overall burden.

The estimated burden to respondents is summarized in Table 12-A and Table 12-B below. There is no annualized burden as this is a onetime data collection to cover the emergency, therefore the burden provided is total. The survey takes an average 10 minutes to complete (**Attachment 2**), preceded by a 4-question screener that is estimated to take about 2 minutes to complete. It is estimated that up to 400 respondents from 15 states will complete the full survey for a total of up to 6,000 respondents. As past 90-day vaping prevalence of THC is estimated to be about 5% (based on published literature,⁷ discussions with subject matter experts, and previous YouGov polling), we estimate that we will need to screen 120,000 individuals in order to achieve our desired maximum sample size of 6,000.

Table 12-A. Estimated Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Individuals	Understanding Vaping Practices in the United States Survey – screening questions (Att. 2)	120,000	1	2/60	4,000
Individuals	Understanding Vaping Practices in the United States Survey – full survey (Att. 2)	6,000	1	10/60	1,000
Total					5,000

⁷ Creamer MR, Wang TW, Babb S, Cullen KA, Day H, Willis G, et al. (2019). “Tobacco Product Use and Cessation Indicators Among Adults — United States, 2018.” *MMWR* 68(45): 1013-1019.

There will be no anticipated costs to respondents other than time. The 2017 U.S. median national hourly wage for all occupations in the U.S. is \$18.12 (see https://www.bls.gov/oes/current/oes_nat.htm#00-0000); since we do not know occupations of all individuals, this was used to represent wages. This wage is assumed for general respondents because of the variety of types of occupations expected.

Table 12-B. Estimated Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Individuals	Understanding Vaping Practices in the United States Survey (Att. 2)	5,000	\$18.12	\$90,600
Total				\$90,600

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

The requested data collection does not impose a financial burden on respondents, nor will respondents incur any expense other than the time spent participating completing the survey. Therefore, there are no additional respondent costs associated with start-up or capital investments. There are also no operational, maintenance, or equipment respondent costs associated with participation in the survey.

14. Annualized Cost to the Government

The estimated average annual cost to the federal government for the proposed information collection activities is \$104,232, which includes CDC staff time/resources and the amount awarded to YouGov to conduct the survey (\$95,000). This figure encompasses 50% FTE for three employees for 3 weeks doing data analysis. It is estimated that three CDC employees (one GS-14 health scientist, one GS-13 health scientist, and one captain in the commissioned corps) will be involved for approximately 50% of their time for three weeks (60 hours) each. The three salaries are \$56.34, \$44.70, and \$52.82 per hour, respectively. The direct annual costs in CDC staff time will be approximately \$9,232 for the analysis period. The average salaries were obtained from the Office of Personnel Management’s website (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2019/general-schedule/>).

Estimated Annualized Cost to the Government per Activity and Total				
Activity	Time in hours required to perform activity	Number of employees performing activity	Average hourly wage of staff reviewing data	Total Estimated Yearly Cost
Data analysis	60	3	\$51.29	\$9,232
Total				\$9,232

The total cost to the government over the study period is \$104,232.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Table 16A - Project Time Schedule

Activity	Time Schedule
Data collection	1 week after OMB approval
Data analysis	1 months after OMB approval
Generation of report	1.5 months after OMB approval

Data analysis will focus on identifying results of the key questions. States, and potentially the public, will only receive summarized and analyzed data and not raw data.

Table 16B - Inclusion criteria

Characteristics of Study Sample
18+ years of age
Resident of one of 15 selected states
Self-report vaping or dabbed marijuana or THC (the psychoactive compound in marijuana) at least five times in the last 3 months
Have not been diagnosed with EVALI in past year

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. Authorizing Legislation: Public Health Service Act
2. Survey: Understanding Vaping Practices in the United States
3. Background and rationale for EVALI survey questions
4. Privacy Impact Assessment (PIA)
5. EVALI survey invitation
6. EVALI consent form
7. EVALI IRB Docs - Determination
8. Lung Injury Response 2019 Assurance of Confidentiality (AoC)