DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

November 25, 2019

Dominic Mancini
Deputy Director
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC

Subject: Request for Emergency Review and Clearance

Dear Mr. Mancini:

Pursuant to Office of Management and Budget (OMB) procedures established at 5 CFR Part 1320, Controlling Paperwork Burdens on the Public, I request that the proposed information collection project, "2019 Lung Injury Response Understanding Vaping Practices in The United States" be processed in accordance with section 1320.13, Emergency Processing.

I have determined that this information must be collected prior to the expiration of time periods established under Part 1320, and that this information is essential for CDC's emergency response in the investigation of e-cigarette, or vaping, product use associated lung injury (EVALI) , and to assist each state/local/territory jurisdiction in making rapid, practical decisions for actions to prevent and control this public health problem.

In early August 2019, initial cases of EVALI were reported to CDC. As of November 13, October 31, 2019, 2,172 EVALI cases have been reported in 49 states, the District of Columbia, and two U.S. territories; 42 deaths have been reported among these cases. 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). 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. 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. Further, there is insufficient data for guiding the selection of controls for a rigorous case-control study (lack of uniformity in demographic characteristics and product brands and types).

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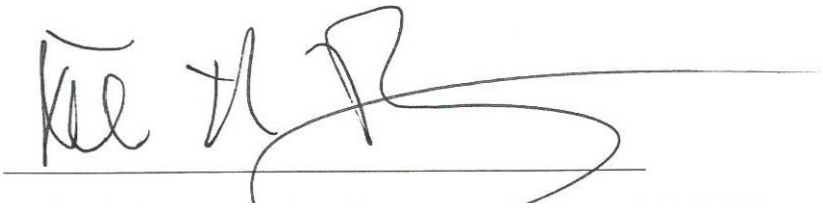
CDC cannot reasonably comply with the normal clearance because our initial investigation suggests that collection of data comparing cases of people who report vaping THC but have not developed EVALI in a timely way is essential for narrowing the list of products, substances, and risk factors requiring further public health investigation and action (e.g., prioritizing samples for laboratory testing). Because the collection of data is expected to begin as soon as possible, accelerated OMB review is requested. Therefore, CDC requests a 90-day emergency clearance to launch collection of data.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business on November 25, 2019.

Respectfully,



Peter Briss, MD
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