Juul Labs®

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By Electronic Submission

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2020-N-0597; Request for Information on Vaping Products Associated with Lung Injuries

To whom it may concern,

Juul Labs, Inc. (JLI or the Company) appreciates the opportunity to provide comment in response to the Food and Drug Administration's (FDA or the Agency) Request for Information (RFI) on Vaping Products Associated with Lung Injuries.[1]

The 2019 outbreak of vaping-related lung injuries demonstrates not only the critical role of public-health authorities in responding to these serious, novel events, but also the importance of evidence-based health-policy communications amid that response. The medical condition referred to as "e-cigarette, or vaping, associated lung injury" (EVALI) emerged from a spate of acute respiratory illnesses among users of vapor products beginning in the summer of 2019. At the outset and through the investigation led by federal and state public-health authorities, there was confusion on the types of products at issue and the stark differences between incidence rates among users of illicit, unregulated cannabis-based products and those among users of authentic, regulated tobacco-derived nicotine products.

Ultimately, both FDA and the Centers for Disease Control and Prevention (CDC) determined that the most likely root cause of EVALI was the use of vapor products containing tetrahydrocannabinol (THC), largely from informal sources, with the ingredient vitamin E acetate.[2] A subset of these products also included components, including cartridges designed for ENDS, which could be modified or altered by the user to add substances (e.g., THC) that are not intended by the manufacturer.

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[1] 85 Fed. Reg. 8875 (Feb. 18, 2020).

[2] *See* FDA Statement, Statement on Consumer Warning to Stop Using THC Vaping Products amid Ongoing Investigation into Lung Illnesses (Oct. 4, 2019), http://bit.ly/32NJFEK; CDC, Transcript of December 20, 2019 Telebriefing: Update on Lung Injury Associated with E-cigarette Use, or Vaping (Dec. 20, 2019), https://bit.ly/3dSfOzE.

Yet to this day, many continue to believe that authentic, FDA-regulated electronic nicotine delivery systems (ENDS) contributed to EVALI cases. Even the congressional prompt for this RFI highlights the continued confusion on what caused EVALI and how to develop an effective regulatory and public-health response: To solicit information on "the recent pulmonary illnesses reported to be associated with the use of e-cigarettes and vaping products."[3] As the Agency has acknowledged, "e-cigarettes" refer specifically to ENDS products that deliver an aerosolized nicotine-containing e-liquid when inhaled.[4] The products at the center of the EVALI outbreak, however, were not authentic ENDS and are not even regulated by the Agency — that is, THC-containing products that are often sold on the black market.

The direct negative public-health impact of illicit, unregulated THC-containing products is now clear: severe respiratory complications resulting in hundreds of hospitalizations and dozens of deaths across the country. But the lack of precision in health and scientific communications during the investigation also directly impacted risk perceptions of ENDS products for adult consumers, particularly smokers, relative to combustible cigarettes.

An increasing number of adult smokers now are less likely to perceive noncombustible alternative products like ENDS as potentially less harmful than combustible cigarettes, despite FDA's stated objective to shift the trajectory of tobacco-related death and disease by moving current adult users down the risk continuum for nicotine delivery.[5] In turn, they are less likely to transition and completely switch from combustible cigarettes to these noncombustible products; or for those who have switched, they may revert to combustible cigarettes.[6] Moreover, market indicators suggest that

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[3] Further Consolidated Appropriations Act, 2020, Public Law 116-94, § 785 (2019).

[4] *See, e.g.*, FDA, Guidance for Industry: Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization 9–10 (April 2020), http://bit.ly/36xppIv ("Enforcement Priorities Guidance").

[5] FDA News Release, "FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death" (July 27, 2017), available at https://bit.ly/3dLcRkx; *see also* S. Gottlieb, "Protecting American Families: Comprehensive Approach to Nicotine and Tobacco" (June 28, 2017), available at https://bit.ly/30BeTQn; S. Gottlieb & M. Zeller, "A Nicotine-Focused Framework for Public Health," 377 New England J. of Med. 111 (2017).

[6] *See, e.g.*, A. Persoskie et al., "Perceived Relative Harm of Using E-cigarettes Predicts Future Product Switching Among US Adult Cigarette and E-cigarette Dual Users," 114 Addiction 2197, 2202 (2019) ("In this national study of US adult dual users of e-cigarettes and cigarettes in 2014–15, those who perceived e-cigarettes as less harmful than cigarettes were more likely to switch to exclusive e-cigarette use, more likely to remain dual users and less likely to switch to exclusive smoking 1 year. Our findings highlight the concern that perceptions of e-cigarettes could potentially deter complete switching to e-cigarettes among some US adult smokers."); *see also* Altria Group, Inc., Earnings Call Transcripts (First Quarter, 2020), https://bit.ly/2YgCeFw ("Over the last several months, we've observed an increase in the number of aged 50 and older smokers in the cigarette category. We believe these smokers have previously switched to e-vapor

historical cigarette volumes and sales declines from 2018–2019 have moderated since the EVALI outbreak, corresponding with significant reversals in ENDS volumes and sales.[7] For example, based on syndicated market data, average annual declines in cigarette sales volumes were the following pre-EVALI: 3.6% (2017); 5.3% (2018); 7.1% (2019 Q1); and 8.1% (2019 Q2). During the EVALI outbreak and immediately since, declines reversed to 7.2% (2019 Q3); 6.6% (2019 Q4); and 5.3% (2020 YTD).

Tellingly, according to Dave and colleagues, at the outset of the EVALI outbreak and following communications from CDC, there was a significant increase in respondents' perception that ENDS products were more harmful than combustible cigarettes.[8] When CDC corrected its messaging and focused on THC-containing products, risk perceptions improved but only slightly.[9] Similarly, in a Reuters/Ipsos poll conducted in September 2019, in the middle of the EVALI investigation, 63% of adults in the United States disagreed with the statement that "vaping is healthier than traditional cigarettes," up 16 percentage points from a similar poll conducted in the spring of 2016.[10]

These trends are problematic in isolation, given the growing evidence emphasizing that nicotine delivery without combustion (e.g., ENDS) is less harmful than delivery with combustion (e.g., cigarettes). They also have the long-term effect of undermining key policy objectives to reduce the harm associated with combustible use as evidenced in the Agency's landmark "Comprehensive Plan on Tobacco and Nicotine Regulation" issued in 2017 and subsequent regulatory priorities.[11]

This comment provides FDA with additional information on these critical issues. First, we provide a summary of the government's investigation, which concluded that

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products but recently returned to cigarettes due to negative publicly and regulatory and legislative developments in the e-vapor category.").

[7] *See, e.g.*, "Older Vapers Are Turning Back to Cigarettes, Marlboro Maker Says," *Wall St. J.* (April 30, 2020), https://on.wsj.com/3hiFZkY (referring to statements from Altria Group, Inc. that older smokers who had switch to ENDS products are reverting to combustible cigarettes because of "negative news coverage and regulatory crackdowns on vaping"); *see also* Management Science Associates, Inc., "Total Nicotine Trends" (Mar. 9, 2020).

[8] *See* D. Dave et al., "News That Takes Your Breath Away: Risk Perceptions During an Outbreak of Vaping-Related Lung Injuries," Nat'l Bureau of Economic Research Working Paper 26977 (2020), https://bit.ly/2Ym1XLn.

[9] *See id.* at 17 ("[T]his downward revision was partial and substantially smaller than the upward revision during the early phase of the outbreak suggesting some stickiness in harm perceptions once they have been adjusted upwards. Hence, overall, belief that nicotine e-cigarettes are more harmful than cigarettes remained significantly higher (by 13.7 percentage points) even after messaging had zeroed in on THC as the cause of the lung injuries.").

[10] *See* "More Americans Say Vaping Is as Dangerous as Smoking Cigarettes: Reuters Poll,' Reuters (Sept. 24, 2019), https://reut.rs/3hglfKL.

[11] *See, e.g.*, S. Gottlieb & M. Zeller, "A Nicotine-Focused Framework for Public Health," 377 New England J. of Med. 111 (2017).

vaping-related lung injuries were most likely associated with the use of THC-containing products, often with the ingredient vitamin E acetate, and its corresponding public statements. Second, we discuss the importance of evidence-based health-policy communications during an event like the EVALI outbreak and their impact on media, individual risk perceptions, and policy. Third, JLI offers recommendations to help ensure that a public-health outbreak similar to EVALI does not actually occur with ENDS products, including on product-design features.

No nonuser, especially those who are underage, should start using nicotine products, including ENDS. But for the 34 million current adult smokers, noncombustible products like ENDS provide a potentially less harmful alternative form of nicotine delivery, and stakeholders should take care not to undermine such viable options as the scientific community and marketplace better understand their impact on public health. Accurate, reliable, and evidence-based communications from public-health officials, particularly during an event like EVALI, are essential to that objective.

I. SUMMARY OF THE GOVERNMENT'S INVESTIGATION ESTABLISHING THE LINK BETWEEN THC-CONTAINING PRODUCTS AND EVALI AND EVOLVING PUBLIC STATEMENTS

The federal and state investigations into EVALI have evolved since their inception in the summer of 2019. Although government agencies, led by CDC and FDA, continue to study these issues, information collected by the public-health authorities now points to the use of THC-containing products, specifically with the ingredient vitamin E acetate, as highly associated with, if not the primary cause of, these lung injuries. The timeline, however, indicates that public statements during the investigation caused confusion on the likely cause of EVALI cases.

A. Timeline of the EVALI Investigation

Federal and state agencies began investigating reported incidents of severe lung injury associated with the use of vapor products in the summer of 2019.[12] Illinois state officials announced the first death from what would later be referred to as EVALI on August 23, 2019, at which point 193 cases across twenty-two states had been documented.[13] One week later, on August 30, 2019, CDC issued its first official health advisory on EVALI for the public and healthcare providers, in which CDC provided background information on the reported cases and recommendations for clinicians, public health officials, and the public.[14] In the document, CDC advised the public to refrain from using "e-cigarette products" while

[12] "Mystery lung illness linked to vaping. Health officials investigating nearly 100 possible cases." *Wash. Post* (Aug. 16, 2019), https://wapo.st/2ML6Ms6.

[13] Ctrs. for Disease Control and Prevention (CDC), "Transcript of August 23, 2019, Telebriefing on Severe Pulmonary Disease Associated with Use of E-cigarettes" (Aug. 23, 2019), https://bit.ly/3cOoAgz.

[14] CDC, "Severe Pulmonary Disease Associated with Using E-Cigarette Products" (Aug. 30, 2019), https://bit.ly/2zr1y1W.

the investigation was ongoing.[15] CDC also advised the public not to buy "e-cigarette products . . . off the street (e.g., e-cigarette products with THC, other cannabinoids)" and "not to modify e-cigarette products or add any substances to these products that are not intended by the manufacturer."[16]

In parallel, both CDC and FDA continued to test product samples received from consumers, patients, hospitals, and state offices as part of the investigation.[17] In these early stages, the evidence became clearer that many, if not most, reported lung-injury cases involved vapor products that were being used to deliver illicit substances such as THC through the use of THC-containing products as sold or by users adding substances to products that were not intended by manufacturers.[18]

As the investigation progressed, federal and state efforts focused on illicit vapor products used to inhale THC as a central factor in the lung-injury cases. In a teleconference on September 6, 2019, CDC announced that some laboratories had identified vitamin E acetate, used as a thickening agent in illicit vaping products containing THC, as a chemical of interest based on samples collected from products used by patients.[19] Shortly after this announcement, the New York governor announced that the state health department would issue subpoenas to three companies manufacturing thickening agents for THC-containing vapor products.[20] And in a CDC telebriefing, FDA disclosed that its Office of Criminal Investigations was conducting a parallel probe in addition to other federal and state agency investigative efforts.[21] While FDA began to tailor its messaging to refer only to adult use of

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[15] *Id.*

[16] *Id.*

[17] *See generally* FDA, "FDA Sample Collection Criteria and Information for Vaping Related Incidents," https://bit.ly/3dPGalK.

[18] *See, e.g.*, FDA Statement, "Statement on federal and state collaboration to investigate respiratory illnesses reported after use of e-cigarette products" (Aug. 30, 2019), https://bit.ly/2y1f5fi ("In many cases, patients have also acknowledged recent use of tetrahydrocannabinol (THC)-containing e-cigarette products while speaking to healthcare personnel, or in follow-up interviews by health department staff."); CDC, "Severe Pulmonary Disease Associated with Using E-Cigarette Products" (Aug. 30, 2019), https://bit.ly/2zr1y1W (discussing use of e-cigarette products with illicit substances, including individuals filling manufacturer pods with illicit substances, and "dripping" and "dabbing" as methods used to increase concentration of THC and other illicit substances in inhaled vapor).

[19] CDC, "Transcript of September 6, 2019, Telebriefing: Investigation of Pulmonary Disease Among People Who Use E-cigarettes" (Sept. 6, 2019), https://bit.ly/2XNFojA; *see also* "Contaminant found in marijuana vaping products linked to deadly lung illnesses, tests show," *Wash. Post* (Sept. 6, 2019), https://wapo.st/2BcIAg2.

[20] *E.g.,* "New York to subpoena firms selling substances linked to illicit vaping products," *Wash. Post* (Sept. 9, 2019), https://wapo.st/3cKJayA.

[21] CDC, "Transcript of CDC Telebriefing: Update on Lung Injury Associated with E-cigarette Product Use, or Vaping" (Sept. 19, 2019), https://bit.ly/3fcVvxc.

THC-containing products in early September 2019,[22] CDC continued to recommend against the use of all vapor products, including ENDS, throughout the remainder of the month.[23]

In October 2019, FDA continued to refine its communications on the potential cause of vaping-related lung injuries, while CDC continued to convey mixed messages about which types of products were implicated (i.e., THC-containing products versus ENDS products). For example, in an October 4, 2019 report published in conjunction with Illinois and Wisconsin public-health authorities, CDC specifically acknowledged that illicit THC-containing cartridges, including those manufactured by Dank Vapes, appeared to be associated with EVALI cases.[24] On the same day, FDA issued a strengthened public warning against THC-containing products and any illicit vaping product obtained off the street.[25]

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[22] *See, e.g.,* FDA, "Tetrahydrocannabinol (THC)-containing Vaping Products: Vaping Illnesses" (Sept. 6, 2019), https://bit.ly/2XUIUJj ("While the FDA does not have enough data presently to conclude that Vitamin E acetate is the cause of the lung injury in these cases, the agency believes it is prudent to avoid inhaling this substance. Because consumers cannot be sure whether any THC vaping products may contain Vitamin E acetate, consumers are urged to avoid buying vaping products from the street, and to refrain from using THC oil or modifying/adding any substances to products purchased in stores."); "FDA Regulation of Electronic Nicotine Delivery Systems and Investigation of Vaping Illnesses," Testimony of N. Sharpless, H. Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations (Sept. 25, 2019), https://bit.ly/2AmTMWN ("While the investigation is ongoing, we strongly encourage consumers to help protect themselves and avoid buying vaping products of any kind on the street, and to refrain from using THC oil or modifying/adding any substances to products purchased in stores.").

[23] *See, e.g.,* J. Schier et al., "Severe Pulmonary Disease Associated with Electronic-Cigarette-Product Use — Interim Guidance," 68 Morbidity and Mortality Weekly Rep. 787, 789 (Sept. 13, 2019), https://bit.ly/2V02XUI ("While this investigation is ongoing and the definitive cause of reported illnesses remains uncertain, persons should consider not using e-cigarette products."); CDC Press Release, "THC Products May Play a Role in Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping" (Sept. 27, 2019), https://bit.ly/2AqiDZZ ("Based on this recent data, CDC recommends people consider refraining from use of e-cigarette or vaping products, particularly those containing THC.") ; @CDCgov, Twitter (Sept. 27, 2019, 3:58 PM) https://bit.ly/2YmLxST ("Lung injury assoc. w/ e-cigarette product use/vaping was recently reported in most states. CDC & others continuing to investigate. CDC recommends considering refraining from using e-cigarette/vaping products, especially those with THC").

[24] I. Ghinai et al., "E-cigarette Product Use, or Vaping, Among Persons with Associated Lung Injury — Illinois and Wisconsin, April–September 2019," 68 Morbidity and Mortality Weekly Rep. 865 (Oct. 4, 2019), https://bit.ly/2wp4jiB; *see also* CDC, "Transcript of CDC Telebriefing: CDC Update on Pulmonary Illnesses" (Sept. 27, 2019), https://bit.ly/3hiDnUc.

[25] FDA, "Vaping Illness Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Vaping Products and Any Vaping Products Obtained Off the Street" (Oct. 4, 2019), https://bit.ly/30yB8X1 ("Do not use vaping products that contain THC. Do not use vaping products — particularly those containing THC — obtained off the street or from other illicit or social sources. Do not modify or add any substances, such as THC or other oils, to vaping products, including those purchased through retail establishments."); *see also* FDA Statement, "Statement on consumer warning to stop using THC vaping products amid ongoing investigation into lung illnesses" (Oct. 4, 2019), http://bit.ly/32NJFEK ("As this complex investigation continues, we urge consumers to take heed of our warning and stop using THC vaping products, and to not use vaping products of any kind that are purchased off the street or from unknown sources.").

Despite this, CDC continued to warn the public to refrain from using of all vapor products, including ENDS, throughout October 2019.[26]

Table 1 provides a timeline of key CDC and FDA statements on EVALI through October 2019. The timeline highlights how long it took for CDC to adjust its messaging to accurately reflect the evidence on which specific types of products were implicated in vaping-related lung-injury cases (i.e., THC-containing products as opposed to ENDS products).

Table 1: Key Government Statements During the EVALI Investigation (Aug. – Oct. 2019)[27]	
08.30.2019	"While the investigation is ongoing, if you are concerned about these specific health risks, consider refraining from using e-cigarette products." – CDC, "Severe Pulmonary Disease Associated with Using E-cigarette Products"
09.06.2019	"While the FDA does not have enough data presently to conclude that Vitamin E acetate is the cause of the lung injury in these cases, the agency believes it is prudent to avoid inhaling this substance. Because consumers cannot be sure whether any THC vaping products may contain Vitamin E acetate, consumers are urged to avoid buying vaping products from the street, and to refrain from using THC oil or modifying/adding any substances to products purchased in stores. Additionally, no youth should be using any vaping product, regardless of substance." – FDA, "Tetrahydrocannabinol (THC)-containing Vaping Products: Vaping Illnesses"
09.13.2019	"While this investigation is ongoing and the definitive cause of reported illnesses remains uncertain, persons should consider not using e-cigarette products." – J. Schier et al., "Severe Pulmonary Disease Associated with Electronic-Cigarette-Product Use — Interim Guidance," in CDC's *Morbidity and Mortality Weekly Report*
09.25.2019	"While the investigation is ongoing, we strongly encourage consumers to help protect themselves and avoid buying vaping products of any kind on the street, and

[26] *E.g.,* C. Perrine et al., "Characteristics of a Multistate Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping – United States, 2019," 68 Morbidity and Mortality Weekly Rep. 860 (Oct. 4, 2019), https://bit.ly/3fzStDj ("While this investigation is ongoing, CDC recommends that persons consider refraining from using e-cigarette, or vaping, products, particularly those containing THC."); D. Siegel et al., "Update: Interim Guidance for Health Care Providers Evaluating and Caring for Patients with Suspected E-cigarette, or Vaping, Product Use Associated Lung Injury – United States, October 2019," 68 Morbidity and Mortality Weekly Rep. 919 (Oct. 18, 2019), https://bit.ly/30TwcMr ("CDC recommends that persons should not use e-cigarette, or vaping, products that contain tetrahydrocannabinol (THC). At present, CDC recommends persons consider refraining from using e-cigarette, or vaping, products that contain nicotine."); CDC, "Transcript of CDC Telebriefing: Lung Injury Investigation" (Oct. 25, 2019), https://bit.ly/2Yr3AY8 ("As such, we recommend that you do not use e-cigarette, or vaping, products that contain THC. And since the specific compounds or ingredients causing lung injury are not yet known, the only way to be sure that you are not at risk is to consider refraining from use of all e-cigarette, or vaping, products while our investigation continues.").

[27] *See supra* notes 12–26 and accompanying text.

Table 1: Key Government Statements During the EVALI Investigation (Aug. – Oct. 2019)[27]	
	to refrain from using THC oil or modifying/adding any substances to products purchased in stores." – Testimony of Acting FDA Commissioner N. Sharpless before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations
09.27.2019	"Based on the recent data, CDC recommends people consider refraining from use of e-cigarette or vaping products, particularly those containing THC." – CDC Press Release, "THC Products May Play a Role in Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping"
09.27.2019	"Lung injury assoc. w/ e-cigarette product use/vaping was recently reported in most states. CDC & others continuing to investigate. CDC recommends considering refraining from using e-cigarette/vaping products, especially those with THC." – CDC, Twitter (@CDCgov)
10.04.2019	"Do not use vaping products that contain THC. Do not use vaping products — particularly those containing THC — obtained off the street or from other illicit or social sources. Do not modify or add any substances, such as THC or other oils, to vaping products, including those purchased through retail establishments." – FDA, "Vaping Illness Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Vaping Products and Any Vaping Product Obtained Off the Street"
10.04.2019	"While this investigation is ongoing, CDC recommends that persons consider refraining from using e-cigarette, or vaping, products, particularly those containing THC." – CDC, Characteristics of a Multistate Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping – United States, 2019
10.18.2019	"CDC recommends that persons should not use e-cigarette, or vaping, products that contain tetrahydrocannabinol (THC). At present, CDC recommends persons consider refraining from using e-cigarette, or vaping, products that contain nicotine." – D. Siegel et al., "Update: Interim Guidance for Health Care Providers Evaluating and Caring for Patients with Suspected E-cigarette, or Vaping, Product Use Associated Lung Injury – United States, October 2019," in CDC's *Morbidity and Mortality Weekly Report*
10.25.2019	"As such, we recommend that you do not use e-cigarette, or vaping, products that contain THC. And since the specific compounds or ingredients causing lung injury are not yet known, the only way to be sure that you are not at risk is to consider refraining from use of all e-cigarette, or vaping, products while our investigation continues." – CDC, "Transcript of CDC Telebriefing: Lung Injury Investigation"

Thereafter, evidence on the link between THC, vitamin E acetate, and lung injuries continued to strengthen as the investigation progressed. On November 8, 2019, CDC announced in a conference call that it had confirmed vitamin E acetate as a potential toxin of interest in biological samples collected from patients.[28] Based on our review, this conference call was the first time CDC publicly focused its warnings on THC-containing products.[29] Further evidence of the association between EVALI and use of THC-containing products including vitamin E acetate has been published in later CDC reports.[30]

B. Current Public Health and Scientific Perspective on EVALI

The current state of scientific and medical understanding of EVALI points to a high correlation between vaping-related lung injuries and the use of illicit products with THC and other cannabis derivatives, including the misuse of ENDS products against manufacturers' instructions and expectations.[31] Recent CDC statements on the status of the EVALI investigation emphasize that a minority of EVALI patients reported use of only nicotine-containing vapor products and that there were reporting-related issues for these

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[28] CDC, "Transcript of CDC Telebriefing: Update on Lung Injury Associated with E-cigarette Use, or Vaping" (Nov. 8, 2019), https://bit.ly/30BE0Cm.

[29] *Id.* ("The results reinforced previous CDC recommendations to not use e-cigarette or vaping products that contain THC, particularly from informal sources like friends or family, online dealers or the illicit market."). As noted previously, CDC's prior recommendations encompassed *all* vapor products, *including* those containing THC.

[30] *See, e.g.*, B. Blount et al., "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," 68 Morbidity and Mortality Weekly Rep. 1040 (Nov. 15, 2019), https://bit.ly/2RirYbK ("Vitamin E acetate was detected in all 29 patient BAL samples. Among 23 patients for whom self-reported THC use information was available, 20 reported using THC-containing products. THC or its metabolites were detected in 23 of 28 patient BAL samples, including in those of three patients who said they did not use THC products."); J. Taylor et al., "Characteristics of E-cigarette, or Vaping, Products Used by Patients with Associated Lung Injury and Products Seized by Law Enforcement — Minnesota, 2018 and 2019," 68 Morbidity and Mortality Weekly Rep. 1096, 1097 (Nov. 27, 2019), https://bit.ly/2Rnd9Vs ("Among the 46 assessed THC-containing products submitted by 12 patients, the most commonly detected compounds were vitamin E acetate (24, 52%), MCT (20, 43%), CBD (20, 43%), and alpha tocopherol (17, 37%). . . . THC-containing products used by 11 of 12 (92%) patients contained vitamin E acetate, and products from seven (58%) patients contained MCT."); K. Gaub et al., "Patient Characteristics and Product Use Behaviors Among Persons with E-cigarette, or Vaping, Product Use–Associated Lung Injury — Indiana, June–October 2019," 68 Morbidity and Mortality Weekly Rep. 1139, 1140 (Dec. 13, 2019), https://bit.ly/34jz0lM ("Results of this investigation of Indiana EVALI patients were consistent with findings from Illinois that frequently using THC-containing products and obtaining these products through personal contacts has been associated with EVALI. In addition, the high proportion of reported use of Dank Vape products might be important, because these products are largely counterfeit.").

[31] *See, e.g.*, E. Elliot et al., "E-cigarette and Vaping-Associated Lung Injury: What's Lurking Inside!," Anesthesiology (2020), https://bit.ly/3hFJ92y; T. Bhat et al., "An Animal Model of Inhaled Vitamin E Acetate and EVALI-like Lung Injury," 382 New England J. of Med. 1175 (2020); B. Blount et al., "Vitamin E Acetate in Bronchoalveolar-Lavage Fluid Associated with EVALI," 382 New England J. of Med. 697, 703 (2019) ("Data that have been reported to date indicate that vitamin E acetate in the supply of THC-containing products and use among patients with EVALI aligns with the timing of the 2019 EVALI outbreak.").

cases.[32] Moreover, both CDC and FDA continue to focus on vitamin E acetate and illicit THC-containing products in their investigations, although they are exploring other possible contributing factors, including additional chemicals of concern in THC and non-THC products.[33]

CDC and FDA also have tailored their public messaging to focus on the link between lung injury and the use of THC-containing products, illicit or black-market vapor products, and e-liquids containing vitamin E acetate. As noted above, both CDC and FDA previously advised the public against the use of all vapor products, including ENDS.[34] Now, CDC and FDA's webpages on EVALI specifically recommend that "people not use THC-containing e-cigarette, or vaping, products, particularly from informal sources like friends, family, or in-person or online dealers."[35] They also advise that "Vitamin E acetate should not be added to any e-cigarette, or vaping, products" and "people should not add any other substances not

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[32] *See, e.g.*, V. Krishnasamy et al., "Update: Characteristics of a Nationwide Outbreak of E-cigarette, or Vaping, Product Use–Associated Lung Injury — United States, August 2019–January 2020," 69 Morbidity and Mortality Weekly Rep. 90, 91 (Jan. 24, 2020), https://bit.ly/2wsgg7i (noting that patients may not be aware of THC or other compounds in products they report as ENDS, and that some EVALI cases may be misclassified as such); I. Ghinai, "Characteristics of Persons Who Report Using Only Nicotine-Containing Products Among Interviewed Patients with E-cigarette, or Vaping, Product Use–Associated Lung Injury — Illinois, August–December 2019," 69 Morbidity and Mortality Weekly Rep. 84, 85 (Jan. 24, 2020), https://bit.ly/2JO55c5 ("Given the different demographics, clinical presentations, and the lack of any indication of exposure to THC-containing products, the contributing cause or causes of EVALI for persons using only nicotine-containing products might differ from the majority of EVALI patients and warrants further investigation.").

[33] *See* 85 Fed. Reg. at 8876 ("FDA has not found one product or substance that is implicated in all of the cases; however, we do know that THC is present in most of the samples being tested and many of these samples have vitamin E acetate as a diluent. FDA is following all potential leads and is committed to taking appropriate actions as additional facts emerge."); CDC Press Release, "Most EVALI Patients Used THC-Containing Products as New Cases Continue To Decline" (Jan. 17, 2020), https://bit.ly/2XjqZMh ("The EVALI outbreak primarily affects young adults, is driven by the use of THC-containing products from informal sources and is strongly linked to vitamin E acetate.").

[34] *See, e.g.*, CDC, "Severe Pulmonary Disease Associated with Using E-Cigarette Products" (Aug. 30, 2019), https://bit.ly/30tapuT. ("While this investigation is ongoing, if you are concerned about these specific health risks, consider refraining from using e-cigarette products."); C. Perrine et al., "Characteristics of a Multistate Outbreak of Lung Injury Associated with E-cigarette Use, or Vaping – United States, 2019," 68 Morbidity and Mortality Weekly Rep. 860 (Oct. 4, 2019), https://bit.ly/3fzStDj ("While this investigation is ongoing, CDC recommends that persons consider refraining from using e-cigarette, or vaping, products, particularly those containing THC."); D. Siegel et al., "Update: Interim Guidance for Health Care Providers Evaluating and Caring for Patients with Suspected E-cigarette, or Vaping, Product Use Associated Lung Injury – United States, October 2019," 68 Morbidity and Mortality Weekly Rep. 919 (Oct. 18, 2019), https://bit.ly/30TwcMr ("CDC recommends that persons should not use e-cigarette, or vaping, products that contain tetrahydrocannabinol (THC). At present, CDC recommends persons consider refraining from using e-cigarette, or vaping, products that contain nicotine."); FDA Statement, "Statement on federal and state collaboration to investigate respiratory illnesses reported after use of e-cigarette products" (Aug. 30, 2019), https://bit.ly/2y1f5fi.

[35] CDC, "Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products," https://bit.ly/3hiDRtu; FDA, "Lung Injuries Associated with Use of Vaping Products," https://bit.ly/30rkSal.

intended by the manufacturer to products, including products purchased through retail establishments."[36]

Based on the investigation timeline and evidence then available, however, communications from public-health authorities were imprecise and delayed in focusing on THC-containing products. After the agencies disclosed the initial link between THC, vitamin E acetate, and EVALI on or around August 30, 2019, FDA shifted its messaging to focus on THC-containing products within a week, but CDC did not adjust its messaging until over two months later.

Even today, any discussion of EVALI almost necessarily will include references to "e-cigarettes" or "vapor products" generally, despite the lack of reliable evidence linking EVALI cases to these regulated products. Few, if any, public-health communications and media reporting differentiate illicit, unregulated THC-containing products (linked to EVALI) from authentic, regulated ENDS products (not linked to EVALI). This inaccurate messaging is unfortunate but perhaps unsurprising given the initial and widespread confusion on implicated products and the persistent use of "e-cigarette, or vaping, product-use associated lung injury" to describe the public-health outbreak.

II. THE CRITICAL ROLE OF PRECISE, EVIDENCE-BASED HEALTH-POLICY COMMUNICATIONS FROM PUBLIC-HEALTH AGENCIES

The EVALI investigation highlights the integral role played by FDA, CDC, and other federal and state agencies in disseminating public-health information, particularly when there is uncertainty on the etiology of product-related risks the public may face. Such communications must be accurate and based upon the best available science, as the public relies upon such information to understand health risks and, in turn, make health and behavioral decisions. These health-policy communications also can impact broader public-health objectives — in this case, reducing the harms associated with tobacco use and moving adult smokers from one form of nicotine delivery (combustible cigarettes) to a potentially less harmful one (noncombustible alternatives).

A. Importance of Accurate, Reliable, and Evidence-based Communications

Recognizing the importance of accurate, reliable, and objective federal agency communications, Congress passed the Information Quality Act (IQA) in 2000, directing the Office of Management and Budget (OMB) to issue guidelines "that provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information disseminated by" such agencies.[37] As specified in the IQA, the OMB guidelines apply to information disseminated by federal

[36] *Id.*

[37] Pub. L. 106–554, §1(a)(3) [title V, §515] (Dec. 21, 2000), codified at 44 U.S.C. § 3516 note; *see* 67 Fed. Reg. 8452 (Feb. 22, 2002) (OMB Guidelines).

agencies and require that each agency issue its own guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity of the information it disseminates.

Under IQA guidelines issued by OMB and the Department of Health and Human Services (HHS), information disseminated by agencies, among other things, should be "accurate, reliable, clear, complete, unbiased and useful."[38] Under the guidelines, "information" is broadly defined to mean "any communication or representation of knowledge such as facts or data, in any medium or form," including "information that an agency disseminates from a web page."[39] "Dissemination" also is broadly defined to mean "agency initiated or sponsored distribution of information to the public," with certain limited exceptions.[40]

CDC has specified that a wide range of its communications meets the definition of "information" "disseminated" by the agency under the IQA, including journal articles, reports, and similar materials, and oral information, such as speeches, interviews, and expert opinions if representing official agency views, positions, or policies.[41] Likewise, FDA has identified numerous types of agency-issued information that fall within the scope of the IQA, including public communications about risk, and certain press items and publications, such as news releases and frequently asked questions (FAQs).[42]

Many of the statements from federal agencies concerning the EVALI investigation constitute "information" "disseminated" subject to the IQA's rubric. Despite this, information disseminated on EVALI appears to have fallen short of the IQA's standards. Neither CDC nor FDA updated its recommendations in a timely manner in light of their own statements that the risk of vaping-related lung injuries was tied to THC and vitamin E acetate — substances not ordinarily present in authentic ENDS products. Indeed, CDC and FDA continued to recommend that the public refrain from using all vapor products, including ENDS, even as the agencies acknowledged that the available evidence led federal and state investigations to focus on THC-containing products and vitamin E acetate. CDC

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[38] OMB Guidelines; U.S. Dep't of Health and Hum. Servs. (HHS), HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public (Oct. 1, 2002), https://bit.ly/2W747ic (HHS Guidelines).

[39] OMB Guidelines; HHS Guidelines.

[40] *Id.* ("Dissemination does not include distribution intended to be limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; and responses to request for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act or other similar law. This definition also does not include distribution limited to correspondence with individuals or persons, archival records, public filings, subpoenas or adjudicative processes.").

[41] *Id.* Part II.D.II.A

[42] *Id.* Part II.F.III.G.

continued this warning for over two months after it and FDA first acknowledged the likely link between THC and EVALI.[43]

B. Impact of Communications on Media

CDC and FDA statements also affect media coverage, a key channel for information that influences public perceptions about health issues. Here, messaging from CDC and FDA appears to have influenced both the extent and substance of media coverage on the EVALI investigation. While media coverage was at its peak during the beginning of the investigation, by the time CDC and FDA modified their messaging to accurately reflect the evidence, such coverage dropped significantly. These trends emphasize the importance of agency communications reflecting the evidence accurately, as well as being updated in a timely manner once that evidence is further developed.

In the early stages of the investigation, a number of media reports erroneously stated or implied that EVALI was attributed primarily to ENDS products or referred to ENDS products and THC-containing products interchangeably, suggesting they were equally associated with EVALI.[44] These reports reflected FDA and CDC messaging on EVALI at the time. As discussed above, even after CDC's September 6, 2019 announcement, both

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[43] *See supra* Part I.A.

[44] *See, e.g.*, "Dozens of Young People Sickened After Vaping; Physicians Are Stumped," *N.Y. Times* (Aug. 14, 2019), https://nyti.ms/2MOIPAo ("Nearly three dozen young people have been hospitalized around the country in recent weeks for severe respiratory problems after vaping either nicotine or marijuana, stumping doctors treating them. . . . The Illinois, Minnesota and Wisconsin public health departments are investigating these cases and at least 20 additional emergency admissions that doctors suspect are related to vaping some substance, possibly even illegal street drugs or adulterated liquids laced with T.H.C., the ingredient that produces marijuana's high."); "CDC investigates lung illnesses linked to e-cigarette use," *Reuters* (Aug. 18, 2019), https://reut.rs/2MOPrPk ("[CDC] is investigating a "cluster" of lung illnesses linked to e-cigarette use after such cases were reported in 14 states. . . . Since June 28, states have reported 94 possible cases of severe lung illness tied to vaping, with 30 occurring in Wisconsin, according to a CDC statement on Saturday."); "First death reported from lung illness linked to vaping, officials say," *Wash. Post* (Aug. 23, 2019), https://wapo.st/37kOcRg ("Illinois officials said Friday that a person who had recently used an e-cigarette and was hospitalized with severe lung illness had died. The death appears to be the first among a spate of mysterious lung illnesses now under investigation by state and federal health officials in connection to vaping — at least 193 cases in 22 states, many in teens and young adults, according to the Centers for Disease Control and Prevention."); "Mysterious vaping lung injuries may have flown under regulatory radar," *NBC News* (Aug. 27, 2019), https://nbcnews.to/2AoZw2z ("As of Aug. 22, 193 potential vaping-related illnesses in 22 states had been reported to the Centers for Disease Control and Prevention. Wisconsin, which first put out an alert in July, has at least 16 confirmed and 15 suspected cases. Illinois has reported 34 patients, one of whom has died. Indiana is investigating 24 cases."); "City of Milwaukee urges everyone who lives there to stop vaping immediately," *CNN* (Aug. 29, 2019), https://cnn.it/3dPIDN2 ("The city of Milwaukee issued a stern warning to residents: Stop vaping immediately. . . . At least 193 cases of lung illness linked to vaping have been reported in 22 states, a number that's growing fast, the Centers for Disease Control and Prevention said last week.").

CDC and FDA recommended that consumers avoid all vapor products despite growing evidence linking lung injuries to products containing THC and vitamin E acetate.[45]

This confusion among media continued in the months following the agencies' initial communications that focused on THC-containing products with vitamin E acetate — specifically in September and October 2019, the months of heaviest media coverage of the EVALI investigation.[46] By the time CDC and FDA updated their messaging to account for evidence that THC-containing products were most likely associated with EVALI cases, media coverage had decreased significantly.[47]

C. Impact of Communications on Individual Risk Perceptions

Statements from CDC, FDA, and other public-health authorities — either directly or through the media — impact how everyday consumers understand public-health issues, perceive risks, and make behavioral decisions. For example, in a National Bureau of Economic Research (NBER) working paper, Dave and colleagues found that consumer perceptions of risk for ENDS products during the EVALI investigation were closely tied to

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[45] Dave et al., *supra* note 8, at 3; *see supra* Part I.A.

[46] *See, e.g.*, "A sixth person died from vaping-related lung disease. Here's what you need to know," *CNN* (Sept. 12, 2019), https://cnn.it/3cQl6dy ("The federal investigation into the link between vaping and severe lung illnesses is ongoing and has not identified a cause, but all reported cases have indicated the use of e-cigarette products and some patients have reported using e-cigarettes containing cannabinoid products, such as THC."); "U.S. CDC recommends against using vapes with marijuana ingredient," *Reuters* (Sept. 27, 2019), https://reut.rs/2XPy6M9 ("People should stop using e-cigarettes, especially those with marijuana ingredient tetrahydrocannabinol (THC), U.S. public health officials recommended on Friday, as an investigation into illnesses and deaths related to vaping deepens."); "Vaping illnesses top 1,000, an increase of 275 cases, CDC says," *NBC News* (Oct. 3, 2019), https://nbcnews.to/30vIsTe ("The Centers for Disease Control and Prevention has identified 1,080 cases of lung illnesses linked to vaping, an increase of 275 since last week."); "Some patients with vaping-related lung injuries are being hospitalized a second time," *Wash. Post* (Oct. 11, 2019), https://wapo.st/2Yg1dqY ("To help clinicians better diagnose and treat these cases, the CDC released more specific guidelines Friday. The guidelines emphasize a close follow-up of patients because some with only mild symptoms experienced a rapid worsening within 48 hours. The CDC is also recommending that health-care providers strongly advise patients to stop using e-cigarettes or other vaping products. For those with addiction to nicotine or THC products, patients should consider cognitive behavioral therapy and consultation with addiction medicine services, the guidelines state."); "He Tried E-Cigarettes to Quit Smoking. Doctors Say Vaping Led to His Death." *N.Y. Times* (Oct. 14, 2019), https://nyti.ms/2BUFZYq ("Investigators say they have not pinpointed what is making people sick, whether it is the liquid being vaped, a material in vaping devices themselves, or something else. The C.D.C. says that nearly 1,300 people have become ill after vaping.").

[47] Our review of coverage of the EVALI investigation by a sample of five leading news outlets (the New York Times, the Washington Post, CNN, NBC News, and Reuters) shows a precipitous drop in the number of articles covering the investigation after October 2019. During the peak months of news coverage, we identified at least 199 articles substantively discussing the EVALI investigation from the five outlets in September 2019 and 126 articles in October 2019, compared with 82 articles in November 2019, 43 articles in December 2019, and fewer than 20 articles in each month from January through April 2020.

CDC's public recommendations.[48] The authors compared survey data from the 2019 National Cancer Institute's (NCI) Health Information National Trends Survey (HINTS), conducted prior to the EVALI outbreak, with ten panels of data collected from commissioned Google Surveys conducted twice a month between September 2019 and January 2020.[49]

The data showed an increase in the percentage of respondents perceiving ENDS products to be more harmful than combustible cigarettes by around 16 points following the beginning of the outbreak, during which CDC recommended that consumers avoid all vapor products, including ENDS.[50] Specifically:

> [T]he probability of regarding e-cigarettes as more harmful compared with cigarettes increased by 15.9 percentage points following the outbreak. This represents a substantial updating of perceived harm, 175% relative to the mean across all periods period to the outbreak, and about 80% relative to the perceived harm in the [National Cancer Institute's Health Information National Trends Survey (HINTS)] wave directly preceding the outbreak.[51]

As CDC shifted its focus to THC-containing products, rather than vapor products generally, as "play[ing] a major role in the current lung injury outbreak,"[52] that percentage moved downward but only slightly.[53] Notably, "this downward revision was partial and substantially smaller than the upward revision during the early phase of the outbreak suggesting some stickiness in harm perceptions once they have been adjusted overall."[54]

Public opinion polling conducted by the Kaiser Family Foundation (KFF) in October 2019 found that only three out of ten adults believed that ENDS products are a "safer

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[48] Dave et al., *supra* note 8.

[49] *Id.* at 11–13.

[50] *Id.* at 17–19.

[51] *Id.* at 17.

[52] @CDCgov, Twitter (Dec. 10, 2019 5:20 PM), https://bit.ly/3hiEnYs.

[53] Dave et al., *supra* note 8, at 17. Dave and colleagues indicate that CDC changed its position to focus on THC in a December 10, 2019 tweet. *Id.* at 9 ("As the cumulative caseload increased, and investigation centered on a subset of the vaping market as the likely cause, the CDC changed its recommendations. Specifically, on December 10, 2019, the CDC issued a recommendation through Twitter urging individuals to 'not use ecigarette, or vaping, products that contain THC, as data suggest these products play a major role in the current lung injury outbreak.'"). JLI's analysis suggests that CDC changed its public position a month earlier. *See supra* notes 28–30 and accompanying text.

[54] Dave et al., *supra* note 8, at 17.

alternative" for cigarette smokers.[55] Through its Health Tracking Poll, KFF surveyed a nationally-representative cohort of 1,205 adults aged 18 years and older from October 3 – 8, 2019.[56] At the time, as discussed above, FDA had begun refining its messaging linking EVALI specifically to THC-containing products, while CDC's communications continued to lack distinction between THC-containing products and ENDS products.

Relevant here, 59% of respondents had heard "a lot" about "illnesses related to e-cigarettes and vaping," while 21% had heard "some" and 14% had heard "a little."[57] Only 6% had heard "nothing at all."[58]

Table 2: KFF Survey Responses Regarding Awareness of EVALI (Oct. 3–8, 2019)
("Q: How much, if anything, have you heard about illnesses related to e-cigarettes and vaping?")[59]

A lot	Some	A little	Nothing at all	Don't know/ Refused
59%	21%	14%	6%	Not reported

Among the same respondents, only approximately 30% believed "e-cigarettes are a safer alternative for cigarette smokers who are trying to quit smoking."[60] Of current users of tobacco products, including ENDS, less than half believed e-cigarettes are a "safer alternative."[61] These risk perceptions varied by age, with older adults less likely to believe that ENDS are a "safer alternative" than combustible cigarettes.[62]

[55] *See* KFF Health Tracking Poll (Oct. 2019), https://bit.ly/2XQUcy8, at 13 ("KFF Health Tracking Poll"); KKF, Data Note: Public Views on Vaping and E-cigarettes (Oct. 17, 2019), https://bit.ly/3f4fo9A ("KKF Data Note").

[56] *See* KFF Health Tracking Poll.

[57] *See* KFF Data Note.

[58] *See id.*

[59] *See* KFF Health Tracking Poll at 13; KFF Data Note.

[60] *See* KFF Data Note.

[61] *See id.*

[62] *See id.*

Table 3: KFF Survey Responses Regarding Perception of Comparative Health Risks of Combustible Cigarettes and ENDS (Oct. 3–8, 2019)

("Q: Do you think e-cigarettes are a safer alternative for cigarette smokers who are trying to quit smoking, or not?")[63]

Demographic	Yes	No
Total	31%	69%
Current users	44%	56%
Nonusers	26%	74%
18–29 years old	45%	55%
30–49 years old	32%	68%
50–64 years old	27%	73%
65 years and older	21%	79%

Polling from Morning Consult found similar results. In September 2019 and January 2020, Morning Consult conducted a national poll among approximately 2,200 adults which assessed awareness, attitudes, and perceptions on vapor products, with a focus on the recent reporting of vaping-related illnesses. An increasing number of adults believed that ENDS products were "very harmful" in general and more harmful than combustible cigarettes.[64] Notably, far more respondents in the poll attributed vaping-related illnesses to ENDS products than to THC products.[65]

A Morning Consult poll conducted in June 2018 provided some level of baseline on perceptions of general harm and relative harm compared to combustible cigarettes in the absence of EVALI.[66] In the June 2018 poll, 38% of adults believed that "using electronic cigarettes" is "very harmful."[67] Thirty-six percent of respondents viewed ENDS products as

[63] *See* KFF Health Tracking Poll at 13-14; KFF Data Note.

[64] *Compare* Morning Consult, National Tracking Poll # 190935 (Sept. 12–14, 2019) Crosstabulation Results, https://bit.ly/2B1hkRe, at 7 ("September 2019 Morning Consult Survey") (showing that 58% of adults believed ENDS products were "very harmful") *with* Morning Consult, National Tracking Poll # 200172 (Jan. 28–30, 2020) Crosstabulation Results, https://bit.ly/3dSj2TQ, at 8 ("January 2020 Morning Consult Survey") (showing that 65% of adults believed ENDS products were "very harmful").

[65] *See* September 2019 Morning Consult Survey at 19, 23 (showing that 58% attributed deaths from lung disease to "[electronic] cigarettes, such as Juul," versus 34% to "[marijuana] or THC electronic cigarettes"); January 2020 Morning Consult Survey at 20, 24 (showing that 66 % attributed deaths from lung disease to "[electronic] cigarettes, such as Juul," versus 28% to "[marijuana] or THC electronic cigarettes").

[66] *See* Morning Consult, National Tracking Poll # 180639 (June 22–24, 2018) Crosstabulation Results, https://bit.ly/3f4fFJE ("June 2018 Morning Consult Survey").

[67] *See id.* at 70; Y. Murad, "As Vaping-Related Lung Illnesses Worsen, Public Holds E-cigarettes Like JUUL Culpable," *Morning Consult* (Sept. 19, 2019), https://bit.ly/30uXZD1.

less harmful to a person's health than traditional tobacco cigarettes, while 52% of respondents believed using ENDS products is just as or more harmful to a person's health as smoking tobacco cigarettes.[68]

In contrast, the September 2019 and January 2020 polling reflected changes across the board on risk perceptions for ENDS generally and relative to combustible cigarettes, with respondents increasingly believing that ENDS products are more harmful than combustible cigarettes.[69] Moreover, an increasing number of respondents continued to believe that ENDS products were responsible for vaping-related lung injuries rather than the THC-containing products.[70] Table 4 provides a summary of those results, compared to similar questions that were polled in June 2018, well before the EVALI outbreak.[71]

Table 4: Morning Consult Survey Results regarding Comparative Health Risks of Combustible Cigarettes and ENDS[72]

	June 2018	September 2019	January 2020
Electronic cigarettes are "very harmful"	38%	58%	65%
Electronic cigarettes are "just as" or "more" harmful to a person's health than tobacco cigarettes	52%	66%	74%
Electronic cigarettes are "less harmful" to a person's health than tobacco cigarettes	36%	22%	18%
People have died from lung disease relating to using "Electronic cigarettes, such as JUUL"	N/A	58%	66%
People have died from lung disease relating to using "Marijuana or THC e-cigs"	N/A	34%	28%

The collection of opinion and perception research across the EVALI investigation reinforces the impact of, and interplay between, public-health events and subsequent

[68] *See* June 2018 Morning Consult Survey at 78; Murad, *supra* note 67.

[69] *See* June 2018 Morning Consult Survey at 78; Murad, *supra* note 67; *see also* S. Wilson, "E-Cigarettes Increasingly Blamed for Lung Illnesses, As Evidence Points Elsewhere," *Morning Consult* (Feb. 5, 2020), https://bit.ly/2UuePhe.

[70] *See id.*

[71] *See* Murad, *supra* note 67; Wilson, *supra* note 69.

[72] *See* June 2018 Morning Consult Survey at 70, 78; September 2019 Morning Consult Survey at 7, 11, 19; January 2020 Morning Consult Survey at 8, 12, 20.

communications from leading authorities. Following the EVALI outbreak, an increasing number of adults perceive noncombustible alternative products like ENDS as more harmful than the combustible cigarette — a product that will kill one of every two long-term users and which constitute the leading cause of preventable death in the United States. Accordingly, adult smokers may be more likely not to change their tobacco-use behaviors by switching to ENDS products and, instead, continue combustible use.[73]

D. Impact of Communications on Policy

The EVALI outbreak and subsequent agency communications also appear to have played a role in impacting state and local policies for ENDS products. At least eight states issued emergency orders or rules banning either all ENDS products or some ENDS products in response to the developing EVALI outbreak.[74] Several state legislatures have adopted permanent legislation that restricts the availability of ENDS products.[75]

State officials made clear that these emergency and permanent measures were adopted, in part, as a response to the EVALI outbreak. For example, Massachusetts issued a press release accompanying Governor Charlie Baker's emergency order which stated:

> The Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) are currently investigating a multi-state outbreak of lung disease that has been associated with the use of e-cigarettes or vaping products (devices, liquids, refill pods, and/or cartridges). To date, the CDC has confirmed 530 cases of lung injury across 38 states. While many of the patients reported recent use of Tetrahydrocannabinol (THC)-containing products, some reported using both THC and nicotine products. No single product has been linked to all cases of lung disease.[76]

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[73] *See, e.g.,* Persoskie et al., *supra* note 6.

[74] *See* Mass. Comm'r of Public Health, Order of the Mass. Comm'r of Public Health Pursuant to the Governor's Sept. 24, 2019 Declaration of a Public Health Emergency (Sept. 24, 2019), https://bit.ly/2UqREog (Massachusetts); Mich. Dep't of Health and Hum. Servs., Protection of Youth from Nicotine Product Addiction Emergency Rules (Sept. 18, 2019), https://bit.ly/3dS0z9S (Michigan); 20 Mont. Admin. Reg. No. 1879 (Oct. 8, 2019), https://bit.ly/2UqSIIM (Montana); N.Y. Dep't of Health, "18-17 Addition of Subpart 9-3 to Title 10 NYCRR (Prohibition on the Sale of Electronic Liquids with Characterizing Flavors" (Sept. 17, 2019), https://on.ny.gov/30rXqtI (New York); Or. Exec. Order No. 19-09 (Oct. 4, 2019) (Oregon); 216-50 R.I. Code Reg. subch. 15, part 6 (as amended Oct. 4, 2019) (Rhode Island); Utah R. 384-418 (Oct. 2, 2019), https://bit.ly/2XKk0fg (Utah); Wash. Exec. Order No. 19-03 (Sept. 27, 2019), https://bit.ly/3h7jbES (Washington State).

[75] *See, e.g.*, An Act Modernizing Tobacco Control, 2019 Mass. Acts ch. 133 (Nov. 27, 2019), https://bit.ly/2Aag52r (Massachusetts); 2019 N.J. Sess. Law Serv. Ch. 425 (Jan. 21, 2020) (New Jersey); N.Y. Pub. Health. Law §§ 1399-mm-1 – 1399-mm-3 (New York).

[76] Office of Gov. Charlie Baker and Lt. Gov. Karyn Polito, Press Release, "Governor Charlie Baker Declares Public Health Emergency, Announces Temporary Four-Month Ban on Sale of All Vape Products" (Sept. 24, 2019), https://bit.ly/3cLgghB.

Similarly, Judith M. Persichilli, Acting Commissioner of the New Jersey Department of Health, published an article in *MD Advisor* citing the EVALI outbreak as a motivating consideration for the state's permanent legislation on tobacco products, including ENDS:

> The Governor took this urgent action because of the serious rise in lung illnesses related to vaping. As of October 8, 2019, there are 1,299 cases of lung illness reported from 49 states, the District of Columbia and 1 U.S. territory. Twenty-six deaths have been confirmed in 21 states. On October 1, 2019, the New Jersey Department of Health announced the first New Jersey death associated with the national vaping outbreak. The total number of confirmed and probable cases of serious lung disease in the state has risen to 14, including two probable cases. In addition, 32 reports of severe lung illness are currently under investigation. The age of individuals affected range from 15 to 51. All individuals were hospitalized.
>
> The Centers for Disease Control and Prevention and the Food and Drug Administration have not identified any specific e-cigarette or vaping product (devices, liquids, refill pods and/ or cartridges) or substance that is linked to all cases. CDC is recommending that individuals refrain from using e-cigarette or vaping products until more is known about the cause of this illness.[77]

Such examples highlight the impact of federal-agency communications not only on individuals' risk perceptions, but also on decisions by state and local policymakers that can impede adult smokers' access to alternative tobacco products. Moreover, through states' temporary and permanent policy changes, the effects of initial messaging from CDC and FDA persist even though the agencies have updated their positions to more accurately reflect the state of science and evidence on EVALI.

These amplified misperceptions on the relative risk between ENDS products and combustible cigarettes, and the public-policy decisions that arise from those misperceptions, may have far-reaching impacts on public health beyond EVALI. This includes undermining key FDA objectives to reduce the death and disease associated with combustible use.

In 2017, the Agency announced its comprehensive plan for tobacco and nicotine regulation that would "serve as a multi-year roadmap to better protect kids and significantly reduce tobacco-related disease and death."[78] The comprehensive plan, a cornerstone of tobacco harm reduction regulatory policy, was built on the principle that "nicotine — while highly addictive — is delivered through products that represent a

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[77] J. Persichilli, "New Jersey Takes Steps to Address Vaping-Related Illness," 12 MD Advisor, no. 4, at 17 (2019), https://bit.ly/30ujyn5.

[78] *See* FDA News Release, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 27, 2017), https://bit.ly/3dLcRkx.

continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes."[79]

Thus, while combustible cigarettes remain the leading cause of preventable death and disease in the United States, causing more than 480,000 deaths per year, there is the potential to move current adult smokers down the risk continuum for nicotine delivery to potentially less harmful, noncombustible alternative products. And "[there] are already products, such as electronic nicotine delivery systems, that could conceivably deliver nicotine without posing the dangers associated with tobacco combustion."[80]

As the Agency continues to implement its comprehensive plan — soon entering a pivotal stage in which it will assess the net-population impact of innovative, noncombustible products like ENDS — it is essential that FDA ensure its health-policy communications not impede its own public-health objectives.

III. RECOMMENDATIONS TO HELP ENSURE THAT ENDS PRODUCTS DO NOT PRESENT ADDITIONAL HEALTH AND SAFETY RISKS

As discussed above, federal and state authorities, as well as others in public health, have linked vaping-related lung injuries to the use of illicit, unregulated THC-containing products, largely from informal sources, with the ingredient vitamin E acetate. Despite the lack of association with authentic, regulated ENDS products, product-design features coupled with regulatory controls can help ensure a similar event does not occur with these products and that they do not present additional health and safety risks.

First, ENDS manufacturers have an obligation to ensure product integrity and to design and develop their products in a manner that limits product misuse. For example, ENDS products should be designed to restrict the ability of consumers and downstream suppliers to modify or otherwise tamper with such products. This includes restricting both the ability of e-liquid containers (e.g., cartridges) to be filled and refilled by consumers and the marketing of "empty" cartridges that are intended to be filled and refilled.[81] Other product controls should include tamper-proof or -resistant packaging, including blister packaging for e-liquid containers at the product level, and clear instructions for consumers

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[79] *Id.*

[80] Gottlieb & Zeller, *supra* note 11.

[81] JLI commends the Agency for including these "empty cartridges" as part of its comprehensive enforcement against manufacturers and retailers that continue to sell illegally marketed ENDS products without premarket authorization. For example, we note that FDA recently has added Eonsmoke and 4X branded products, including 4X "empty pods," to the "List of firms and their products subject to Detention without Physical Examination (DWPE)" under Import Alert 98-06. *See* FDA, Import Alert 98-06, https://bit.ly/3ehteWf; *see also* FDA, Warning Letter to Eonsmoke, LLC (Oct. 24, 2019) (finding that Eonsmoke illegally marketed nearly 100 ENDS products without premarket authorization, including 4X branded empty pods).

not to refill or tamper with the products. In addition, as part of product stewardship, ENDS manufacturers should apply strict ingredient-clearance principles with appropriate toxicological and analytical testing to avoid including substances like vitamin E acetate with known significant, deleterious health effects in their nicotine-containing e-liquids.

Second, FDA has plenary authority to set requirements for manufacturers and similarly guard against the introduction of tobacco products that could contribute to product contamination and an EVALI-like outbreak. For example, under § 906(e)(1)(A) of the Federal Food, Drug, and Cosmetic Act (FDCA), the Agency has authority to establish manufacturing requirements to ensure "the public health is protected and that the tobacco product is in compliance with [provisions in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act)]."[82] The Company understands that FDA is actively developing rulemaking relating to these Tobacco Product Manufacturing Practice (TPMP) requirements and recommends that it consider design controls and product testing, including in-process and at release, to reduce potential tampering and product contamination. And critically, through the premarket tobacco product application (PMTA) process under FDCA § 910, FDA should evaluate potential product misuses and ensure manufacturers account for such issues in its submission.

Both manufactures and FDA can implement appropriate controls to reduce the likelihood that what occurred with the EVALI outbreak does not happen with authentic, regulated ENDS products. Critically, this includes manufacturers developing a robust product design, testing, and manufacturing process to maintain the integrity of their products and prevent potential misuse to safeguard consumers against additional risk.

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JLI appreciates the opportunity to comment on FDA's RFI on Vaping Products Associated with Lung Injuries. The EVALI outbreak stemmed from the availability and use of illicit, unregulated THC-containing products, largely from informal sources, that use the ingredient vitamin E acetate.

Throughout the investigation, however, statements from public-health authorities muddled the apparent contributing factors of EVALI and lacked precision in distinguishing regulated ENDS products from black-market THC vapor products. In doing so, these health-policy communications missed the requisite rigor and timeliness to reflect the evolving evidence — rigor that should underpin all scientific communications by public-health agencies considering the public health implications at stake.

JLI encourages public-health authorities to adhere to these principles as the Agency continues to develop a comprehensive regulatory approach for moving current adult smokers down the risk continuum to alternative, potentially less harmful products.

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[82] 21 U.S.C. § 387f(e)(1)(A).

Respectfully submitted,