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Strange Clouds: A Discussion of the Recent EVALI Outbreak and the FDA's Approach to Regulating the Vaping Industry

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As the medical field continues to devote much of its attention towards the ongoing COVID-19 pandemic, a new threat to public health has unfortunately emerged—E-cigarettes or Vaping Associated Lung Injury ("EVALI").[1] Although EVALI is a relatively new medical phenomenon, as of February 18, 2020, sixty-eight Americans have died from EVALI, and a reported 2,807 Americans have been hospitalized as a result of the illness.[2] With the number of individuals who vape expected to reach 55 million this year,[3] the vaping industry is in desperate need of uniform, federal regulation aimed at ensuring manufactures adequately warn individuals about the serious health risks associated with vaping.[4]

While an recent article published by the Center for Disease Control ("CDC") concluded that the EVALI outbreak was essentially over after the agency allegedly identified the primary cause of the illness, the data relied upon by the CDC arguably does not support their overly definitive conclusion.[5] To elaborate, after the CDC began periodically collecting data on the illness in early August of 2019, the agency noticed that the number of EVALI related hospitalizations rose dramatically from roughly 30 cases total to just under 240 cases reported in a single day on September 15, 2021.[6] Moreover, it was not until around the same time the CDC limited its collection of EVALI data to cases where the individual was hospitalized or died that the agency began to mention a noticeable decline in the number of reported cases.[7] Further, the CDC only formally collected data on EVALI for just six months before unilaterally deciding to end their investigation.[8] As such, given the briefness of the CDC's investigation and the agency's failure to account for non-hospitalized cases of EVALI, the agency's conclusion is arguably overly definitive and effectively functions to downplay the prevalence of the illness.[9]

When doctors at Yale were observing the first cases of EVALI,[10] the Food and Drug Administration ("FDA") introduced the Deeming Rule which formally established the agency's authority to regulate e-cigarettes and allowed the Center for Tobacco Products ("CTP"), a subsidiary agency of the FDA, to enforce Electronic Nicotine Delivery Systems ("ENDS") regulations as it would over other tobacco products.[11] The FDA claimed to have the power to regulate the vaping industry under the legislative authority Congress delegated to the agency via the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA").[12] Broadly, the Deeming Rule imposed several reporting, registration, and premarket review regulations on ENDS manufactures.[13] While the FDA indicated it would briefly delay enforcement of the premarket review regulations for existing vape products already on the market,[14] new ENDS manufactured after the Deeming Rule's effective date were nevertheless required to apply for FDA review and approval before they could be sold to the

public.[15]

However, in August of 2017, the FDA published official guidelines ("2017 Guidance") that extended review and approval application deadlines to as late as 2022, and effectively allowed ENDS manufacturers to easily avoid the premarket requirements set out in the Deeming Rule.[16] Put differently, instead of addressing the growing public health concerns related to EVALI and other pulmonary illnesses caused by vaping, the 2017 Guidance allowed unapproved vaping products to be manufactured, marketed, and sold for five years or longer without their labels, ingredients, or flavors ever being reviewed or approved by the FDA.[17] As a result, some ENDS labels arguably may not sufficiently warn potential users about the health risks associated with many of the toxic chemicals found in these unapproved products.[18]

Unfortunately, the FDA's lackadaisical approach to regulating the vaping industry went largely unnoticed for almost two years. However, in *American Academy of Pediatrics v. FDA,* the weak regulatory efforts of the agency were exposed after the Plaintiff sued claiming that the FDA violated the TCA by allowing unapproved ENDS to be sold to the public.[19] The District Court agreed with the Plaintiff and vacated the 2017 Guidance after admonishing the FDA for failing to address substances found in unapproved vaping products that are believed to pose an inherent danger to public health.[20] Further, because the 2017 Guidance indicated that the FDA was not going to enforce the premarket review and approval application requirements on any ENDS manufactures, the Court reasoned that the FDA was "abdicating its statutory duty."[21] Regrettably, because the FDA appealed the Court's decision, not much has changed since the case was concluded at the District Court level.[22]

Despite the past failures of the FDA and CDC, the federal government is nevertheless well equipped to have a meaningful impact on the current problems in the vaping industry.[23] While states and municipalities are also permitted to regulate vape products,[24] because the federal government is not plagued by jurisdictional limitations, it has the unique ability to enact uniform regulations that will apply in all 50 states.[25] Further, because there are multiple federal agencies capable of regulating and monitoring the vaping industry, the federal government has the manpower and resources necessary to facilitate the in kind of cooperation required to combat the vaping industry's present problems.[26]

To summarize, while data is scarce, it is undisputed that EVALI and other vaping related illnesses pose a serious threat to public health and should not be taken lightly.[27] However, it is not too late for the federal government to address these public health concerns by enacting the uniform regulations the vaping industry desperately needs. Nevertheless, if federal agencies do not begin to learn from their mistakes, cases of EVALI and other vaping-related illnesses will arguably only become more common until the vaping industry is properly regulated.

[1] Erin Schumaker, *The Vaping Crisis Has a New Name: EVALI,* ABC News, (Oct. 11, 2019), https://abcnews.go.com/ABCNews/vaping-crisis-evali/story?id=66217454 (announcing health officials had a name for lung injuries associated with vaping as EVALI).

[2] *See Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products,* CDC (Feb. 25, 2020, 1:00 PM), https://www.cdc.gov/tobacco/basic_information/e-cigarettes/ severe-lung-disease.html.

[3] Lora Jones, Vaping: How Popular Are E-cigarettes?, BBC News (Sept. 15, 2019), https://www.bbc.com/news/business-44295336.

[4] Sonya Sondhi, The Vaping Reaper: The EVALI Crisis and Why FDA Regulation is Needed to Prevent Further Issues, 17 J. Health & Biomed. L. 119 (2020).

[5] *See* CDC, *supra* note 2.

[6] *See Id.*

[7] *See Id.*

[8] *See Id.*

[9] *See Id.*

[10] *E-cigarette or Vaping Product, Use Associated Lung Injury (EVALI),* Yale Med., https://www.yalemedicine.org/conditions/evali (last visited Dec. 15, 2004).

[11] *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 28,973 (May 10, 2016) (to be codified at 21 C.F.R. pt. 1100; 21 C.F.R. pt. 1140; 21 C.F.R. pt. 1143) (expanding FDA's authority to regulate e-cigarettes); Ned Sharpless, *How FDA is Regulating E-Cigarettes,* FDA (Sept. 10, 2019), https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/how-fda-regulating-e-cigarettes (outlining tactics and strategies the FDA uses to combat youth use of e-cigarettes).

[12] *Id; see also See Family Smoking Prevention and Tobacco Control Act,* Pub. L. No. 111-31, § 901(e), 123 Stat. 1776 (2009).

[13] *Id.*

[14] Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products ("Deeming Rule"), 81 Fed. Reg. 28,974, 28,976 (May 10, 2016).

[15] *Id.*

[16] May 2017 Guidance 7-8, GAR 214-15, ECF No. 48-1, at 695-96; *See* Am. Acad. of Pediatrics v. FDA, 379 F.Supp.3d 461, 468–70 (D. Md. 2019).

[17] *See Am. Acad. of Pediatrics*, 379 F.Supp.3d at 469–72.

[18] *See* Kathleen Raven, *Teen Vaping Linked to More Health Risk*, Yale Med. (Dec. 18, 2019), https://www.yalemedicine.org/news/teen-vaping; *see also Chemicals in Vape*, Vape Danger, https://www.vapedanger.com/health-risks/toxic-chemicals/#:~:text=In%20recent%20years%2C%20scientists%20have%20found%20various%20chemicals,currently%20investigating%20the%20long-term%20health%20effects%20of%20vaping, (last visited Aug. 23, 2021).

[19] *See* Am. Acad. of Pediatrics, 379 F.Supp.3d. at 467–73.

[20] *See Id.* at 492 ("Through the August 2017 Guidance, the FDA is abdicating its statutory duty to review new tobacco products in the prompt fashion dictated by Congress in its *premarket* review requirements.").

[21] *See Id.* at 492.

[22] *See* Jones, *supra* note 4, at 150.

[23] *See Id.* at 139–150.

[24] *See e.g.*, Chris Kirkham et al., *Juul Loses Home Turf as San Francisco Bans E-Cigarette Sales,* Reuters (June 25, 2019), https://www.reuters.com/article/us-usa-sanfrancisco-ecigarettes/juul-loses-home-turf-as-san-francisco-bans-e-cigarette-sales-idUSKCN1TQ2YL; See Michigan Dep't of Health & Human Serv. Bureau of Health & Wellness, Pub. Health Admin., Protection of Youth From Nicotine Products Addiction Emergency Rules (2019), available at https://www.michigan.gov/documents/mdhhs/Emergency_vaping_rules_-_signed_by_Gov-Director_9.18.19_666139_7.pdf; See Prohibition on the Sale of Electronic Liquids with Characterizing Flavors, 41 N.Y. Reg. 15-18 (Oct. 2, 2019) (temporarily amending N.Y. Comp. Codes R. & Regs. tit. 10, § 9-3).

[25] *See* Jones, *supra* note 4, at 144–45.

[26] *See* Jones, *supra* note 4, at 144–55.

[27] Cameron English, *Health Risks of Vaping: Let's Stick to the Science and Speculate Less,* Am. Couns. on Sci. & Health (May 25, 2021), https://www.acsh.org/news/2021/05/25/health-risks-vaping-lets-stick-science-and-speculate-less-15568.

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