

PRODUCT LIABILITY

FEBRUARY 2020

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Shayna S. Cook and Symone D. Shinton report updates on the nationwide regulation and litigation of e-cigarettes. Practitioner insights regarding social media marketing are provided.

Updates on E-Cigarette Litigation and Practitioner Takeaways Related to Social Media Marketing

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Recently, U.S. litigation related to electronic cigarettes (“e-cigarettes” or “ENDS”¹), commonly known as “vapes,” has increased. Meanwhile, the Food and Drug Administration (“FDA”) and other agencies have expanded their regulatory oversight of these products. This article provides an update on those recent developments as well as insights for defense counsel regarding social media marketing of products based on arguments gaining traction in this litigation.

Background on E-Cigarettes

E-cigarettes are sleek and portable electronic devices styled to look like thumb drives or pens. According to the largest manufacturer of e-cigarettes, Juul Labs, Inc. (“Juul”), vapes were intended to replace a smoker’s reliance on traditional tobacco cigarettes while providing the desired effects of smoking. To achieve this, vaping manufacturers introduced what they believed to be a safer and more convenient alternative for their target audience: adult smokers. Juul, which dominates seventy-five percent of the industry with its

notorious USB-shaped product, the “Juul,” is owned in part by Altria Group.² When Altria bought into the company in December 2018, it valued Juul at \$38 billion. As of January 30, 2020, Altria values Juul at \$12 billion, citing an 80% increase in legal actions against Juul since October 31, 2019.³

The lion’s share of the litigation and regulatory action related to e-cigarettes stems from the use of these products by minors. Since August 2016, it has been illegal to sell e-cigarettes to people younger than 18.⁴ But according to the FDA, e-cigarette use amongst high school students has skyrocketed since vapes arrived on the market—as many as 3.6 million minors use e-cigarettes as of 2018,⁵ which one district court called an “epidemic-level use” by teenagers.⁶ No vapes are FDA-approved.⁷ Whether vaping is safer than smoking traditional cigarettes is the subject of ongoing studies and discussion by regulatory agencies and the medical community.⁸ Vape manufacturers like Juul maintain that their products are important, less harmful

¹ Some agencies refer to vapes as “electronic nicotine delivery systems” or ENDS.

² Erin Brodwin, *The Precarious Path of E-Cig Startup Juul: From Silicon Valley Darling to \$24 Billion Behemoth Under Criminal Investigation*, BUSINESS INSIDER (Oct. 31, 2019),

<https://www.businessinsider.com/juul-timeline-from-startup-to-tobacco-company-challenges-bans-2019-9>.

³ Sergei Klebnikov, *Juul Valuation Falls to \$12 Billion As Altria Takes Another \$4.1 Billion Hit*, FORBES (Jan. 30, 2020),

<https://www.forbes.com/sites/sergeiklebnikov/2020/01/30/juul-valuation-falls-to-12-billion-as-altria-takes-another-41-billion-hit/#15a5dbc0f4f2>; Altria Press Release (Jan. 30, 2020),

<http://investor.altria.com/Cache/1001260221.PDF?O=PDF&T=&Y=&D=&FID=1001260221&iid=4087349>.

⁴ U.S. FOOD & DRUG ASS’N, HOW FDA IS REGULATING E-CIGARETTES (2019).

⁵ U.S. FOOD & DRUG ASS’N, 2018 NYTS DATA: A STARTLING RISE IN YOUTH E-CIGARETTE USE (2019).

⁶ *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 498 (D. Md. 2019).

⁷ U.S. FOOD & DRUG ASS’N, VAPING ILLNESS UPDATE: FDA WARNS PUBLIC TO STOP USING TETRAHYDROCANNABINOL (THC)-CONTAINING VAPING PRODUCTS AND ANY VAPING PRODUCTS OBTAINED OFF THE STREET (2019).

⁸ Mohammad Abul Kaiser et al., *A Decade of e-Cigarettes: Limited Research & Unresolved Safety Concerns*, 365 J. TOXICOLOGY, 67-75 (2016).

alternatives to smoking.⁹ Indeed, the former FDA Commissioner acknowledged that vapes may offer an “alternative to cigarettes for adults who still seek access to satisfying levels of nicotine, without all the deadly effects of combustion.”¹⁰ Juul’s litigation position is that “[s]moking kills” and rendering liability for vapes would force “millions of consumers of JUUL products. . . to obtain nicotine through combustible cigarettes,”¹¹ or unsafe black-market vapes.¹²

No one disputes that vaping is still addictive¹³—the aerosol inhaled by vape users contains nicotine (a stimulant from tobacco plants) just like traditional cigarettes.¹⁴ But e-cigarette vapor does not contain tobacco or some of the other chemicals and additives found in cigarettes.¹⁵ To replicate the smoker’s high, e-cigarettes contain other chemicals such as

tetrahydrocannabinol (THC), the principal psychoactive component of cannabis.¹⁶ Vaping is also unquestionably more convenient, as it allows users to achieve a smoker’s high quickly and discreetly. And e-cigarette vapor is designed to taste and smell pleasing, containing a variety of flavors the user may interchange.¹⁷

Beginning in the summer of 2019, hundreds of users of e-cigarettes went to emergency rooms with unique lung injuries now known as EVALI (for e-cigarette or vaping associated lung injury). According to the Centers for Disease Control and Prevention (“CDC”), the chemical of concern is likely vitamin E acetate, a thickening agent often used in illicit vaping products containing THC.¹⁸ But no single compound or ingredient has been conclusively determined to be the cause of

⁹ Brief in Support of Juul Labs, Inc.’s Motion to Transfer Related Cases for Consolidated Pretrial Proceedings Pursuant to 28 U.S.C. 1407 at 2-3, *In re: Juul Labs, Inc., Marketing, Sales Practices, and Products Liability Litigation*, 396 F. Supp. 3d 1366 (N.D. Cal. July 29, 2019) (“JLI’s mission is to improve the lives of the world’s one billion adult smokers by eliminating cigarettes.”).

¹⁰ U.S. FOOD & DRUG ASS’N, STATEMENT FROM FDA COMMISSIONER SCOTT GOTTLIEB, M.D., ON PROPOSED NEW STEPS TO PROTECT YOUTH BY PREVENTING ACCESS TO FLAVORED TOBACCO PRODUCTS AND BANNING MENTHOL CIGARETTES (2018).

¹¹ Defendant Juul Labs, Inc.’s Motion to Dismiss Plaintiffs’ Consolidated Amended Complaint at 1, *In re: Juul Labs, Inc., Marketing, Sales Practices, and Products Liability Litigation*, 396 F. Supp. 3d 1366 (N.D. Cal. Mar. 26, 2019).

¹² See generally *Vapor Tech. Ass’n. v. Baker*, SUCV20193102D, 2019 WL 6050041 (Mass. Sup. Ct. Oct. 21, 2019).

¹³ Mateusz Jankowski et al., *E-Cigarettes are More Addictive than Traditional Cigarettes – A Study in*

Highly Educated Young People, 16 INT. J. ENVIRON. RES. PUBLIC HEALTH 2279 (2019).

¹⁴ U.S. FOOD & DRUG ASS’N, *supra* note 5.

¹⁵ *Public Health Consequences of E-Cigarettes*, NAT’L ACAD. OF SCI. ENG’G AND MED. (Jan. 23, 2018), <http://nationalacademies.org/hmd/Reports/2018/public-health-consequences-of-e-cigarettes.aspx>.

¹⁶ CTR. FOR DISEASE CONTROL AND PREVENTION, OUTBREAK OF LUNG INJURY ASSOCIATED WITH THE USE OF E-CIGARETTE, OR VAPING, PRODUCTS (2020).

¹⁷ Most flavors have been withdrawn from market. *Juul Halts Sales of Fruit, Dessert Flavors for E-Cigarettes, Will Continue Selling Its Most Popular Flavors: Mint and Menthol*, CHICAGO TRIBUNE (Oct. 17, 2019), <https://www.chicagotribune.com/nation-world/ct-nw-juul-ecigarette-fruit-dessert-flavors-20191017-l2qcgga2sana3fhgy5wp3vegwdu-story.html>.

¹⁸ CTR. FOR DISEASE CONTROL AND PREVENTION *supra* note 16. In that study analyzing EVALI patients, forty-eight out of fifty-one patients had vitamin E acetate in their lungs.

EVALI.¹⁹ As of January 14, 2020, the CDC reported a total of 2,711 hospitalizations or deaths due to EVALI. The CDC has continued to monitor EVALI and issue recommendations.

Major health organizations have admonished e-cigarette use. The American Medical Association has called for a total ban on e-cigarettes.²⁰ The American Heart Association has stated that vaping is not safe and “should not be promoted as a safe alternative to smoking.”²¹ The American Cancer Society has called for FDA regulation of e-cigarettes and similarly discourages e-cigarette use by any age group.²²

Operating within this complex framework of inconclusive data and disparate opinions, courts are grappling with novel factual arguments raised through traditional legal theories.

Civil Lawsuits

Even before the recent EVALI outbreaks, parents and school districts filed lawsuits on behalf of teen consumers, including class actions related to marketing and personal injury actions alleging pulmonary disease, seizures, and other problems.²³ In October 2019, the Judicial Panel on Multidistrict Litigation consolidated 55 lawsuits against Juul in an MDL in the Northern District of California.²⁴ That MDL is still in its nascency. Most claims allege vaping companies’ marketing practices targeted youth based on their social media advertisements and kid-friendly flavors.²⁵ These claims are based in statutory and common law fraud and failure to warn. Juul has defended its use of allegedly “kid-friendly” flavors as essential to designing a product that would capture and keep the attention of adult smokers transitioning from traditional cigarettes—an argument the FDA has acknowledged.²⁶

¹⁹ David 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*, 19 AM. J. TRANSPLANT 3420-3428 (2019).

²⁰ *AMA Calls For Total Ban on All Vaping Products Not Approved by FDA*, AMERICAN MEDICAL ASSOCIATION (Nov. 19, 2019), <https://www.ama-assn.org/press-center/press-releases/ama-calls-total-ban-all-vaping-products-not-approved-fda>.

²¹ *Is Vaping Better Than Smoking?*, AMERICAN HEART ASSOCIATION (Oct. 30, 2018), <https://www.heart.org/en/healthy-living/healthy-lifestyle/quit-smoking-tobacco/is-vaping-safer-than-smoking>.

²² *American Cancer Society Position Statement on Electronic Cigarettes*, AMERICAN CANCER SOCIETY, <https://www.cancer.org/healthy/stay-away-from-tobacco/e-cigarette-position-statement.html> (last visited Jan. 30, 2020).

²³ See, e.g., *In re: Juul Labs, Inc., Marketing, Sales Practices, and Products Liability Litigation*, 396 F. Supp. 3d 1366 (N.D. Cal. Oct. 2, 2019); Adeel Hassan, *Juul Is Sued by School Districts That Say Vaping Is a Dangerous Drain on Their Resources*, NEW YORK TIMES (Oct. 7, 2019), <https://www.nytimes.com/2019/10/07/us/juul-vaping-schools.html>.

²⁴ *In re: Juul Labs, Inc., Marketing, Sales Practices, and Products Liability Litigation*, 396 F. Supp. 3d at 1366.

²⁵ Katy Moncivais, *What Are Consumers Claiming in Juul Lawsuits?*, NATIONAL LAW REVIEW (Sep. 11, 2019), <https://www.natlawreview.com/article/what-are-consumers-claiming-juul-lawsuit>; Alex Norcia, *The Netflix Doc ‘Broken’ Shows How Social Media Helped Feed the Vape Crisis*, VICE (Dec. 3, 2019), https://www.vice.com/en_us/article/7x5gib/netflix-doc-broken-shows-how-social-media-helped-feed-the-vape-crisis.

²⁶ Defendant Juul Labs, Inc.’s Motion to Dismiss Plaintiffs’ Consolidated Amended Complaint at 4, *In*

Other lawsuits focus on the product itself, alleging that vapes are actually more addictive than cigarettes and unsafe in their own right.²⁷ These allegations support product liability claims sounding in strict liability, negligence, and failure to warn of the health risks associated with vaping. At least some of these product liability claims have survived motions to dismiss.²⁸

With respect to advertisements, at least one district court denied motions to dismiss material omission claims alleging that vape manufacturers withheld information about the negative health effects associated with ingredients in the vapor.²⁹ Claims based on the advertisements giving the false impression that vapes were altogether safe, however, were dismissed.³⁰ Juul has also successfully argued that certain labeling-related claims are preempted by The Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”), whereby Congress gave the FDA exclusive regulatory authority as to e-cigarettes.³¹ But fraud and

failure to warn claims based on advertisements, exempt from the Tobacco Control Act’s explicit preemption clause, were held to be not preempted,³² and survived motions to dismiss.³³

Defending against claims based on the product, Juul has raised identity and intervening causation arguments, pointing to third party counterfeit products. According to Juul, these counterfeits are not just a threat to their market share, but the lower-quality products are also responsible for the health injuries.³⁴ This particular argument finds some support from the FDA and CDC, given that the vitamin E acetate apparently responsible for the EVALI outbreak is absent from Juul’s cartridges but present in its counterfeit counterparts.³⁵ Notably, one court rejected this intervening cause argument at the motion to dismiss stage on the basis that Juul may have had reason to foresee the creation of a counterfeit market for its products, even if

re: Juul Labs, Inc., Marketing, Sales Practices, and Products Liability Litigation, 396 F. Supp. 3d 1366 (N.D. Cal. Mar. 26, 2019); See U.S. FOOD & DRUG ASS’N, *supra* note 10 (acknowledging that the availability of certain flavors “may be important to adult smokers seeking to transition away from cigarettes”).

²⁷ Stanton A. Glantz, *Class Action Lawsuit Filed Against Juul and Altria/Philip Morris Builds on Past Litigation against Big Tobacco*, CTR. FOR TOBACCO CONTROL RESEARCH AND EDUC. (Apr. 16, 2019), <https://tobacco.ucsf.edu/class-action-lawsuit-filed-against-juul-and-altriaphilip-morris-builds-past-litigation-against-big-tobacco>.

²⁸ See, e.g., *Colgate v. Juul Labs, Inc.*, 402 F. Supp. 3d 728, 754-755 (N.D. Cal. 2019) (analyzing consumer-expectations and risk-utility tests).

²⁹ *In re Fontem US, Inc. Consumer Class Action Litig.*, 2016 WL 11503066, No. SACV 15-01026 JVS(RAOx), at *9 (C.D. Cal. Apr. 22, 2016).

³⁰ *Id.* at *44-45.

³¹ Order Partially Granting Motion to Dismiss and Denying Motion to Strike at 8-11, *Colgate v. Juul Labs, Inc.*, No. 18-cv-02499-WHO (N.D. Cal. Oct. 30, 2018).

³² Order Granting Motion to Dismiss in Part and Denying Part; Denying Motion to Compel; Discovery Letter; Motion to Seal at 2, *Colgate v. Juul Labs, Inc.*, No. 3:18-cv-02499-WHO (N.D. Cal. Aug. 23, 2019).

³³ *Id.* at 17-20.

³⁴ See, e.g., *Juul Labs, Inc. v. Unincorporated Ass’n Identified in Schedule A*, 2019 WL 4419337, No. 18-cv-01516, at *3 (E.D. Vir. Aug. 15, 2019).

³⁵ Robert Langreth, *More Evidence Links Vaping Lung Injuries to Vitamin E Acetate*, BLOOMBERG (Dec. 20, 2019), <https://www.bloomberg.com/news/articles/2019-12-20/more-evidence-links-vaping-lung-injuries-to-vitamin-e-acetate> (suggesting Vitamin E acetate is the “main culprit in the outbreak”).

that conduct is illegal.³⁶ Product liability claims have generally survived motions to dismiss.³⁷

Federal and State Regulatory Developments

Three agencies are involved in the oversight of e-cigarettes: the FDA, CDC, and the Federal Trade Commission (“FTC”). These agencies are not operating in a legislative vacuum. The Congressional landscape developed to address combustible tobacco cigarettes, The Tobacco Control Act enacted by Congress in 2009, has since expanded to include vaping as of 2016. The Tobacco Control Act requires manufacturers of various nicotine products to apply for and obtain premarket authorization (“PMA”) before introducing new products into interstate commerce for commercial distribution.³⁸ Though originally granted deferral status until 2022, vapes are now permitted to remain on the market without

an application for FDA PMA approval until May 12, 2020.³⁹ Once an application is submitted, the vape may remain on the market without PMA approval for an additional year while the FDA renders a decision.⁴⁰

The FDA has taken several measures to regulate vaping. The FDA has extensively enforced its rule prohibiting sales to minors both online and in retail stores.⁴¹ In 2018, the FDA raided Juul’s San Francisco office and seized thousands of documents to determine whether Juul knowingly targeted youth.⁴² And in September 2019, FDA sent a warning letter to Juul based on its statements that e-cigarettes are safer than tobacco cigarettes.⁴³ The FTC has similarly investigated vape manufacturers, issuing “orders” (functionally, interrogatories) to six companies seeking to collect information regarding their promotional practices.⁴⁴ An investigative decision is expected at the end of Q1FY20.⁴⁵ The CDC has also played an

³⁶ See *Colgate*, 402 F. Supp. 3d at 762 (“Plaintiffs’ allegations, if proven, are sufficient to show that Juul had reason to know that its conduct would encourage illegal use and trade of its products; thus, the allegedly illegal activity was foreseeable and not an intervening cause.”).

³⁷ See Order Partially Granting Motion to Dismiss and Denying Motion to Strike at 27-28, *Colgate v. Juul Labs, Inc.*, No. 18-cv-02499-WHO (N.D. Cal. Oct. 30, 2018).

³⁸ 21 U.S.C. § 387j(a)(1)-(2), (b)(1) (2010); 21 C.F.R. § 1100, 1140, 1143 (2016).

³⁹ U.S. FOOD & DRUG ASS’N, ENFORCEMENT PRIORITIES FOR ELECTRONIC NICOTINE DELIVERY SYSTEMS (ENDS) AND OTHER DEEMED PRODUCTS ON THE MARKET WITHOUT PREMARKET AUTHORIZATION (2020).

⁴⁰ *Id.*

⁴¹ The FDA has issued more than 8,000 warning letters, and, as part of the largest coordinated enforcement effort in FDA history, it initiated 131 Civil Money Complaints against retailers who

violated the rule. U.S. FOOD & DRUG ASS’N, FDA TAKES NEW STEPS TO ADDRESS EPIDEMIC OF YOUTH E-CIGARETTE USE, INCLUDING A HISTORIC ACTION AGAINST MORE THAN 1,300 RETAILERS AND 5 MAJOR MANUFACTURERS FOR THEIR ROLES PERPETUATING YOUTH ACCESS (2018).

⁴² Ankur Banerjee et al., *FDA Seizes Documents from Juul in Latest E-Cigarette Crackdown*, REUTERS (Oct. 2, 2018), <https://www.reuters.com/article/us-usa-fda-cigarettes/fda-seizes-documents-from-juul-in-latest-e-cigarette-crackdown-idUSKCN1MC26P>.

⁴³ U.S. FOOD & DRUG ASS’N, WARNING LETTER TO JUUL LABS, INC. (2019).

⁴⁴ U.S. FED. TRADE COMM., FTC TO STUDY E-CIGARETTE MANUFACTURER’S SALES, ADVERTISING, AND PROMOTIONAL METHODS (Oct. 3, 2019).

⁴⁵ Angelica LaVito, *Altria Confirms FTC Investigation of Juul as Agency Scrutinizes Role in Executive Shake-up At Vaping Company*, CNBC (Oct. 31, 2019), <https://www.cnbc.com/2019/10/31/altria-confirms-ftc-probe-of-juul-as-agency-scrutinizes-executive-shakeup.html>.

investigatory role, working with state departments to gather and publish information, including about EVALI.⁴⁶

States responses have ranged from advisories against vaping⁴⁷ to full-blown lawsuits.⁴⁸ Some states are still investigating the issue,⁴⁹ whereas others still have issued support in favor of vape manufacturers.⁵⁰ A recent publication in JAMA found that state regulations may be associated with reduced e-cigarette use among adults.⁵¹ This tapestry of state responses should be expected unless and until the federal government regulates vaping more extensively.

Practitioner Insights: Social Media Marketing

The e-cigarette litigation highlights the potential of social media to support fraud and failure to warn claims.⁵² Courts have refused to extend social media accountability to monitoring how unaffiliated third parties promote their products, even if these promotions increase sales.⁵³ But at least one court has suggested that companies that use social media to promote their products may have a duty to monitor whether minors engage with their platform.⁵⁴ Federal agencies are also paying attention to social media advertisements. When one pharmaceutical company partnered with Kim Kardashian to promote their drug on Instagram, the FDA issued a warning letter regarding the content of the post.⁵⁵

⁴⁶ CTR. FOR DISEASE CONTROL AND PREVENTION, CHARACTERISTICS OF MULTISTATE OUTBREAK OF LUNG INJURY ASSOCIATED WITH E-CIGARETTE USE, OR VAPING – UNITED STATES (2019).

⁴⁷ See, e.g., *Illinois Attorney General Consumer Alert to Avoid Using E-Cigarettes or Vape Products* (Aug. 30, 2019), http://www.illinoisattorneygeneral.gov/pressroom/2019_08/20190830.html.

⁴⁸ See, e.g., Merrit Kennedy, *North Carolina Says It Is Suing 8 E-Cigarette Companies*, NPR (Aug. 27, 2019), <https://www.npr.org/2019/08/27/754717176/north-carolina-says-it-is-suing-8-e-cigarette-companies>.

⁴⁹ See, e.g., *Florida's Attorney General Launching Vaping Investigation*, AP NEWS (Oct. 16, 2019), <https://apnews.com/2ce7f6596ede4113bd5c52fe21207bff>.

⁵⁰ *Iowa Attorney General Still Supports E-Cigarettes Despite Vaping Illnesses, Anti-Tobacco Legacy*, THE GAZETTE (Oct. 31, 2019), <https://www.thegazette.com/subject/news/health/vaping-illness-e-cigarette-ban-juul-iowa-tom-miller-attorney-general-20191031>.

⁵¹ Yang Du et al., *Association of Electronic Cigarette Regulations With Electronic Cigarette Use Among Adults in the United States*, 3(1) JAMA NETWORK OPEN 1920255 (Jan. 31, 2020).

⁵² See *In re Fontem US, Inc. Consumer Class Action Litig.*, No. SACV 15-01026 JVS(RAOx), 2016 WL 11503066, at *14 (C.D. Cal. Apr. 22, 2016) (screenshots of social media campaigns depicting e-cigarette as “clean” and “healthy” attached as exhibits to complaint).

⁵³ *Colgate*, 402 F. Supp. 3d at 760 (third-party accounts used the same hashtag promoted by the defendant vape manufacturer).

⁵⁴ *Id.* at 754 (“It is reasonable to infer that companies such as JUUL with large social media presences *assiduously monitor* the use of popular hashtags involving their name. It would have seen numerous posts of minors using their product. . . It is inconceivable that the company was unaware of how its products were being used by minors, based on the amount of social media content minors posted of themselves using JUUL’s”).

⁵⁵ U.S. FOOD & DRUG ASS’N, WARNING LETTER TO DUCHESNAY, INC. (2015); see also Suzanne Zuppello,

With respect to what is “reasonable” to expect of companies, defense counsel must educate themselves and the court on the technological limitations of social media. For example, companies may not even be able to monitor the ages of their audience—Instagram does not display or verify the age of users.⁵⁶ And although companies utilizing Instagram can set a “minimum age limit” on their content,⁵⁷ nothing is stopping minors from entering a fake birthdate.⁵⁸

Product claims based on social media ads will not be limited to the e-cigarette litigation. As these arguments continue to develop in the courts, in-house counsel should be aware that statements made through social media campaigns and influencers may be highlighted in courts and give rise to liability. Product liability defense lawyers will want to continue to watch regulatory and litigation developments involving e-cigarettes as this unique area continues to evolve.

The Latest Instagram Influencer Fronteir? Medical Promotions, Vox (Feb. 15, 2019), <https://www.vox.com/the-goods/2019/2/15/18211007/medical-sponcon-instagram-influencer-pharmaceutical>.

⁵⁶ Kara Yurieff, *Instagram Will Now Ask New Users to Provide Their Age*, CNN BUSINESS (Dec. 4, 2019),

<https://www.cnn.com/2019/12/04/tech/instagram-age-requirement/index.html>.

⁵⁷ Help Center, INSTAGRAM,

<https://help.instagram.com/307876842935851>.

⁵⁸ Yurieff, *supra* note 56.

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