Labs., 3 F.3d 643, 646 (2d Cir. 1993) (holding that point sources are "physical structures and instrumentalities that systematically act as a means of conveying pollutants from an industrial source to navigable waterways"); *Rice v. Harken Expl. Co.*, 250 F. 3d 264, 271 (5th Cir. 2001) (holding that any effort to construe the CWA to cover pollutants that reach navigable waters by "gradual, natural seepage" through groundwater would be an "unwarranted expansion of the [statute]"); *Vill. of Oconomowoc Lake v. Dayton Hudson Corp.*, 24 F.3d 962, 965 (7th Cir. 1994) (refusing to extend CWA liability to cover pollutants seeping into "local ground waters" that may be hydrologically connected with surface waters).

Moreover, in addition to the recent Circuit Courts of Appeals' decisions, the issue continues to be litigated in the district courts. In September 2018, the U.S. District Court for the District of Massachusetts rejected an argument that a landfill that discharged to groundwater was a point source that required a permit under the Act. *Toxic Action Ctr., Inc. v. Casella Waste Sys., Inc.*, No. 17-40089, 2018 WL 4696750, at *4–6 (D. Mass. Sept. 30, 2018) (amended order issued on October 3, 2018). In rejecting the plaintiffs' arguments, the Court recognized the Sixth Circuit's decision in *Kentucky Utilities* and *TVA*, specifically citing to the Circuit's discussion of the CWA's jurisdiction as it relates to groundwater. *Id.* at *5 n.3. Moreover, the Court noted that the "[t]he Frist Circuit has not addressed whether a discharge of a pollutant that moves through ground water before reaching navigable waters may constitute a discharge of a pollutant, within the meaning of the CWA." *Id.* at *5. In November 2018, the U.S. District Court for the Central District of Illinois dismissed a case in which an environmental group sought to extend CWA liability to a corporation based on a groundwater connection from its coal ash ponds to the Middle Fork River. *Prairie Rivers Network v. Dynegy Midwest Generation, LLC*, No. 18-2148, 2018 WL 6042805 (C.D. Ill. Nov. 14, 2018). In doing so, the district court held that it was bound by the Seventh Circuit's decision in *Village of Oconomowoc Lake*. These district courts—like the Second, Fifth, Sixth, and Seventh Circuit—read the text and legislative history of the Act as evidencing a conscious political choice to restrict the reach of the Act to navigable surface waters in deference to the states' power to regulate groundwater pollution.

Regardless of whether the Supreme Court takes up these questions this term, the opinions by the Fourth, Sixth, and Ninth Circuits raise important questions for a wide range of industrial, commercial, and municipal operations, among others, as well as state regulatory agencies. Arguably thousands of discharges to groundwater currently not covered by the CWA's National Pollutant Discharge Elimination System (NPDES) permitting program could be required to obtain NPDES permits if the logic of *County of Maui* and *Upstate Forever* is expanded or adopted nationwide.

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FDA Focuses on Youth E-Cigarette Use as Juul Comes Under Fire in Civil Litigation

By Oded Burger, Jessica Butkera, and Jason Botticelli



The FDA's target on the e-cigarette industry, and its specific focus on Juul—a California-based company whose exponential growth secured a 73 percent market share in the $2.5 billion American e-cigarette market—has been palpable and aggressive in 2018. Between raiding Juul's headquarters and launching a comprehensive ad campaign aimed at eliminating youth vaping, the FDA is forcing Juul's hand, which is already shaky from a string of

lawsuits against it, to make major changes to its business practices.

The FDA started strong in 2018 with an April sting operation that specifically targeted marketers and retailers of Juuls, including gas stations, convenience stores and online shops like eBay. In less than two months, the FDA issued warning letters and fines to approximately forty retailers that it says violated the law meant to prevent sales of vaping devices to individuals under the age of 21. By late summer, that number increased more than 1,300.

In August, the FDA then announced its intent to "quickly advance" three new initiatives concerning tobacco and vapor products. In a joint blog post on August 2, Scott Gottlieb, commissioner of the FDA, and Mitch Zeller, director of the FDA's Center for Tobacco Products, pronounced that the FDA was expediting action against flavored products, developing an e-cigarette product standard, beginning to explore various ways to accelerate enforcement of the marketing of vapor products to youth, as well as youth access. The next day the FDA released new draft guidance looking for nonclinical information to support development and approval of orally inhaled nicotine-containing drug products.

Within the next month, the FDA announced it was giving five tobacco companies (including Juul) sixty days to submit plans describing how they will address youth access and use of their products. FDA letters to manufacturers dated September 12 made clear that noncompliance or unsatisfactory compliance could result in the removal of "some or all of their flavored products that may be contributing to the rise in youth use from the market until they receive premarket authorization and otherwise meet all of their obligations under the law."

While Juul responded to media inquiries for a statement on this letter and publically indicated its willingness to work with the FDA, the FDA did not sit idly by awaiting a formal response. Just days later on September 28, the FDA raided Juul's SF headquarters and seized thousands of pages of documents relating to marketing practices. After it caught Juul by surprise, the FDA sent letters two weeks later to twenty-one other e-cigarette companies seeking information about whether more than forty tobacco products—including flavored e-cigarette products—are being illegally marketed outside the agency's current compliance policy.

The FDA started the year's fourth quarter by unveiling one of its more aggressive ad campaigns in recent history. On October 18, the FDA launched "The Real Cost" Youth E-Cigarette Prevention Campaign. Modeled after its 2014 "The Real Cost" Anti-Smoking Campaign—a $247 million antismoking campaign that studies show prevented nearly 350,000 youth from becoming cigarette smokers, saving the nation $31 billion in mortality, earnings loss, and other costs—this updated campaign seeks to educate teens about the dangerous effects of using electronic cigarettes. From television commercials to posters in thousands of school bathrooms, the public service campaign targets nearly 10.7 million young people ages twelve to seventeen who have used e-cigarettes or are open to trying them.

Within one month, the FDA went from ad campaigns to action. On November 9, the FDA threatened regulations banning the sale of most flavored e-cigarettes at retail locations and requiring anyone buying e-cigarettes online to verify their age. After the mere mention of these regulations, coupled with a Wall Street Journal report suggesting that the FDA was also prepared to ban the sale of menthol cigarettes, sent U.S.-focused tobacco stocks tumbling the following Monday, the FDA released more limited regulations. On November 15, the agency said it would allow stores to continue selling such flavored products, but only from closed off-areas that would be inaccessible to teenagers. FDA-head Gottlieb said what he is "envisioning is a separate room or a walled-off area . . . it needs to be a complete separate structure. A curtain won't cut it." While a ban on menthol cigarettes will take years to develop and will be met with insurmountable resistance from the tobacco industry, the agency confirmed its intention to outlaw both menthol cigarettes and flavored cigars.

Juul clearly felt the brunt of the FDA's weight and publically responded. Admitting youth e-cigarette use was a serious issue, CEO Kevin Burns wrote "we want to be the off-ramp for adult smokers to switch from cigarettes, not an on-ramp for America's youth to initiate on nicotine." He then outlined an action plan to address youth use of its products. First, Juul stopped accepting retail orders for attractive fruit-flavored pods, *i.e.*, mango, fruit, creme, and cucumber, from the over 90,000+ retail stores that sell Juul. Second, it revamped its online store to include additional protections, such as a two-factor authentication, which verifies a user's identity through their phone number, and then requires a code sent to that phone to create an account. In addition to third-party verification of a purchaser's name, date of birth, permanent address, and the last four digits of their social security number, Juul is adding a real-time photo requirement to match a user's face against an uploaded I.D. Third, Juul will strengthen its retail compliance by increasing its secret shopper program to brick-and-mortar stores and monitoring third-party online

marketplaces to limit the sale of Juul products in violation of their terms-of-service and standards. Finally, in what is likely a direct response to the FDA's raid, Juul is eliminating its social media accounts and monitoring and removing inappropriate material from third-party accounts.

Juul Hit with Multiple Civil Lawsuits

Juul's response is proportional to the backlash it has faced this year, both from the FDA and by class action lawsuits. To date there are five class actions filed against Juul across the country. The first was a national class action filed in April of 2018 in the Northern District of California, which defined the class as anyone who purchased a Juul product in the United States, and further alleging a subclass of those persons were minors at the time of the purchase. *Colgate v. JUUL Labs, Inc.*, No. 3:18-cv-02499. Thereafter, several duplicative class actions were also filed in New York, Florida, Pennsylvania, and New Jersey, but those actions have been the subject of motions to dismiss under the "First Filed" doctrine. Additionally, a California State class action was filed to accommodate those class action plaintiffs who lack diversity of citizenship with the California based company, but those state claims are subject to an informal stay allowing the *Colgate* action to proceed first.

The primary allegation in these civil suits is that owing to Juul's use of benzoic acid in its nicotine vaping solution, their vaping device delivered a more potent dose of nicotine than regular cigarettes, thus allegedly deceiving those who are seeking to quit the use of cigarettes into further addiction. Moreover, plaintiffs have alleged that Juul's patented nicotine vaping solution contains 6.2 percent nicotine, rather than the 5 percent that was noted on the product labeling. Premised on those facts, the *Colgate* plaintiffs raised 11 causes of action sounding in (1) False Advertising; (2) Violation of Consumers Legal Remedies Act, California Civil Code §§1750, *et seq.*, and similar laws of other states; (3) Fraud; (4) Unfair, Unlawful and Deceptive Trade Practices, Business and Professions Code §17200 and similar laws of other states; (5) Unjust Enrichment, (6) Strict Liability – Failure to Warn; (7) Strict Product Liability – Design Defect; (8) Strict Liability – Manufacturing Defect; (9) Breach of Implied Warranty of Merchantability; (10) Breach of Express Warranty; and (11) Negligent Misrepresentation.

In July of this year, Juul moved to dismiss the claims in *Colgate* on the grounds that plaintiffs' claims were preempted under the Federal Food, Drug, and Cosmetic Act as amended by the Tobacco Control Act (TCA). By an order dated October 30, 2018, Judge William H. Orrick agreed that the alleged product mislabeling which relates to the pharmacokinetics of benzoic acid and nicotine salt solutions were expressly preempted under federal law, but the allegations of product mislabeling arising from a 20 percent higher nicotine concentration than advertised were not. In reaching that finding, Judge Orrick noted that an individual "who believes they might wean themselves off of traditional cigarettes by using Juul's products may, in fact, be consuming the equivalent of four more cigarettes per pod." Judge Orrick additionally followed a finding by California Central District Court Judge James V. Selna, who held that the TCA preemption applied retroactively to claims which occurred prior to its enactment on August 8, 2016. *See In Re Fontem US, Inc. Consumer Class Action Litig.*, 15- CV-01026 (C.D. Cal. March 8, 2017), Dkt. No. 110. However, Judge Orrick found that claims based on deceptive advertising, as opposed to product mislabeling, were not subject to preemption pursuant to an advertising exception in the preemption clause of the TCA.

Juul additionally moved for a dismissal based on the plaintiffs' failure to plead sufficient facts in their complaint. On those grounds, Judge Orrick further dismissed with prejudice the plaintiffs' claims sounding in fraudulent advertising under the heightened pleading requirements of FRCP 9(b) as a result of plaintiffs' failure to plead specific allegations about which of Juul's advertisements were false, misleading, or unfair. Similarly, Judge Orrick dismissed plaintiffs' claims sounding in unspecified state consumer protection laws and express warrantees, albeit without prejudice to a more robust amended pleading. Lastly, Plaintiffs' claims related to California-based consumer protection statutes, unjust enrichment, design defect, manufacturing defect, implied warrantees, negligent misrepresentation, were all allowed to proceed primarily on the basis that the Court was compelled to accept as true the allegation that Juul understated the concentration of nicotine in its vaping pods and plaintiffs relied on its representation that each pod contained an equivalent amount of nicotine to a pack of cigarettes.

Future of Regulation of E-Devices

It is anticipated that in the coming months and year, the FDA will continue its crackdown of youth e-cigarette use. However, this is not the only area that will need to be addressed with e-cigarettes. The FDA has its hands full in keeping up with and regulating the ever changing technology, juices and new uses of e-devices too. Last October, the FDA sent out letters to certain vape companies warning against selling vape liquids that contain Viagra. They have

also had to deal with the new trend of "vitamin vaping," which is where a vitamin liquid is used with an electronic delivery system. Many of the vitamin vape liquids do not contain nicotine. This means the liquid would most likely not be regulated as a tobacco product. However, the electronic delivery systems are regulated as tobacco products as the definition of what includes a "tobacco product" in the FDA's regulatory guidelines includes delivery systems and component parts. The vitamin liquids also do not appear to fall under the category of a "dietary supplement" as the liquids are vaporized and inhaled and not ingested, as required by definition. The vitamin liquids are a hybrid product that fall somewhere between a "supplement" and a "tobacco product." The FDA will need to figure out how to treat such products as they enter the market place.

When technology changes so quickly, regulations are usually playing catch-up. It will be interesting to see how the FDA's targeted campaign against youth e-cigarette use and the civil actions shape the relatively new e-cigarette industry and how new uses of e-devices, such as vitamin vaping, will be regulated.

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