UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

Moose Jooce, et al., Plaintiffs, v. **Food and Drug Administration**, et al., Defendants.	No. 18-cv-203 CRC Hon. Christopher R. Cooper United States District Judge
Rave Salon, Inc., d/b/a Joosie Vapes, Plaintiff, v. **Food and Drug Administration**, et al., Defendants.	No. 18-cv-1615 CRC
Jen Hoban d/b/a Masterpiece Vapors, et al., Plaintiffs, v. **Food and Drug Administration**, et al., Defendants.	No. 19-cv-372 CRC

MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN SUPPORT OF GOVERNMENT'S CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT

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I. Introduction

Electronic cigarettes are the fastest growing segment of the tobacco market, and their use has spiked dramatically in recent years. They are now used by more than 20% of high school students, eclipsing conventional cigarettes as the most popular tobacco product among youth. And they present significant public health risks. To start, they are designed to deliver nicotine — one of the most addictive substances known to man — and can do so as effectively as conventional cigarettes. Nicotine is toxic — it impairs brain development in youth, causes pre-term delivery and stillbirth, and can be fatal at high doses. Some e-cigarettes also deliver other toxic and carcinogenic chemicals at levels higher than conventional cigarettes. Others have exploded in users' faces, causing burns and lost teeth. And while the ingredients of the thousands of e-liquids on the market are largely unknown, many contain toxic chemicals that are especially common in candy-flavored varieties that appeal to youth.

In a rule issued in 2016, the U.S. Food and Drug Administration exercised its statutory authority to deem e-cigarettes subject to regulation as tobacco products under the Family Smoking Prevention and Tobacco Control Act. This commonsense approach to addressing the significant public health risks posed by e-cigarettes — including the "epidemic levels of e-cigarette use by kids"[1] — has been repeatedly endorsed since its rollout by both the Secretary of Health and Human Services and the FDA Commissioner

[1] HHS Secretary Alex M. Azar & FDA Commissioner Scott Gottlieb, M.D., *The Future of E-Cigarettes Depends on the Industry's Willingness to Protect Teens*, Wash. Post, Mar. 20, 2019, https://www.washingtonpost.com/opinions/2019/03/19/future-e-cigarettes-depends-industrys-willingness-protect-teens/.

and was ratified by the only two Senate-confirmed FDA Commissioners to serve in the years since.

Nevertheless, some two years after the deeming rule took effect, the plaintiffs seek to invalidate the rule — and short-circuit the FDA's regulation of e-cigarettes as tobacco products — based solely on the identity of the agency official who signed the rule. They claim that the signing official — Associate Commissioner for Policy Leslie Kux — was not a validly appointed officer under the Appointments Clause. As explained below, the plaintiffs' Appointments Clause claim fails on the merits because Ms. Kux was a duly appointed inferior officer. But the Court need not even reach the merits of that claim because it has been forfeited: The plaintiffs failed to raise any challenge to Associate Commissioner Kux's authority to sign the rule during the rulemaking comment period.

Even if not forfeited, any alleged defect was cured when either of two FDA Commissioners subsequently ratified the rule. The plaintiffs contend that one of those ratifications was ineffective because it failed to address studies released *after* the final deeming rule was issued supposedly showing that e-cigarettes are not as dangerous as previously thought. But the plaintiffs do not even address the other ratification, which by itself conclusively resolves the Appointments Clause claim. Nor was the Commissioner's ratification required to address those subsequent studies — which in any event reported results similar to earlier studies considered and addressed by the agency.

On the merits, the Appointments Clause claim fails because the deeming rule was issued by a duly appointed inferior officer. The Associate Commissioner for Policy is subject to substantial direction, supervision, and removal authority by the Secretary of

Health and Human Services and the FDA Commissioner and is thus an inferior officer. And Ms. Kux was duly appointed to that position pursuant to congressional authorization by the HHS Secretary, a "Head[] of Department[]" under the Appointments Clause. Summary judgment should therefore be granted for the government on the Appointments Clause claim.

II. Background

A. Congress studies the dangers of tobacco products and the industry's marketing practices

Congress passed the Tobacco Control Act based on evidence compiled over decades by all three branches of government about the health risks of tobacco products and the tobacco industry's marketing practices. That evidence established four key points.

First, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000).[2] "Each year, 440,000 people die of diseases caused by smoking or other forms of tobacco use — that is about 20 percent of all deaths in our nation." Statement of Vice Admiral Richard H. Carmona, U.S. Surgeon General, reprinted at 155 Cong. Rec. S6000 (June 3, 2009).

Second, the magnitude of the public health harm caused by tobacco use is "inextricably linked" to nicotine addiction. 75 Fed. Reg. 69,524, 69,528 (Nov. 12, 2010). "The pharmacologic and behavioral processes that determine tobacco addiction are

[2] For the Court's convenience, citations to legal authorities and docket entries in the PDF version of this brief are linked to the cited authorities in Westlaw and ECF, respectively.

similar to those that determine addiction to drugs such as heroin and cocaine." *Id*. The power of nicotine addiction is perhaps best illustrated by the failure rate of cessation efforts. In 2004, over 40% of adult smokers reported trying to quit, but only 3–5% were successful. *Id*. at 69,529. The tobacco industry has long appreciated the importance of nicotine addiction to sales. In an internal 1972 memo, one company acknowledged that "a tobacco product is, in essence, a vehicle for the delivery of nicotine" — a "potent drug with a variety of physiologic effects" — and that the "industry is then based upon the design, manufacture, and sale of attractive forms of nicotine." 146 Cong. Rec. H1849 (Apr. 5, 2000) (statement of Rep. Ganske) (quoting an R.J. Reynolds memo).

Third, the tobacco industry has long depended on recruiting underage users who become addicted before age 18. Congress found that, despite laws prohibiting the sale of tobacco products to minors, the "overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18." Leg. Finding 31, Pub. L. No. 111-31, § 2, 123 Stat. 1776 (2009). Congress also found that "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth." *Id*., Leg. Finding 15.

Fourth, the tobacco industry for decades misled consumers about the health risks and addictiveness of its products. In 1964, the Surgeon General began issuing reports on the health consequences of tobacco use and nicotine addiction. In response, tobacco companies undertook a campaign to deny these health hazards and attack the studies, even though they knew the reports were accurate. These efforts are "demonstrated by not only decades of press releases, reports, booklets, newsletters, television and radio

appearances, and scientific symposia and publications, but also by evidence of their concerted[] efforts to attack and undermine the studies in mainstream scientific publications such as the Reports of the Surgeon General." *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 855 (D.D.C. 2006), *aff'd in part*, 566 F.3d 1095 (D.C. Cir. 2009).

At the same time, tobacco companies sought to develop "health reassurance" products purporting to pose lower health risks, provide an alternative to quitting, or represent a step in decreasing the level of dependence. *Philip Morris*, 566 F.3d at 1107. The companies knew, however, that these ostensibly "modified risk" products actually provided no health benefit. Indeed, tobacco companies "marketed and promoted their low tar brands to smokers — who were concerned about the health hazards of smoking or considering quitting — as less harmful than full flavor cigarettes despite either lacking evidence to substantiate their claims or knowing them to be false." *Id.*

B. Congress enacts the Tobacco Control Act

Against this backdrop, Congress enacted the Family Smoking Prevention and Tobacco Control Act as a comprehensive scheme to regulate tobacco products. Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 301 et seq.). The Act aims to make "consumers ... better informed" about "the health and dependency effects or safety of tobacco products"; to permit the FDA to "regulate the levels of tar, nicotine, and other harmful components" of tobacco products; and to ensure "effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." Pub. L. No. 111-31, § 3(4)–(6). The Act effectuates these goals in three main ways.

First, the Act requires disclosure of accurate information about the ingredients of tobacco products and their health risks. Manufacturers of tobacco products subject to the Act must disclose to the FDA the identity and quantity of all ingredients — including nicotine and any other additives — in each product. 21 U.S.C. § 387d(a)(1)–(2). Product labels must accurately describe their contents. *Id.* § 387c. Tobacco products may be required to bear warnings about their addictiveness and other risks. *Id.* § 387f(d)(1)–(2); 15 U.S.C. § 4402(a)(1). And to ensure that products marketed as having reduced health risks actually do so, Congress required premarket FDA review of tobacco products purportedly posing "modified risks," like lower risk of disease or reduced exposure to harmful substances. 21 U.S.C. § 387k.

Second, the Act regulates the contents of tobacco products. Manufacturers must register with the FDA, *id.* § 387e(b), file a list of tobacco products they make, *id.* § 387e(*i*), and adhere to manufacturing practices the FDA may prescribe, *id.* § 387f(e). Given the appeal of flavored products to children, Congress banned the use of all characterizing flavors (except tobacco and menthol) in cigarettes. *Id.* § 387g(a)(1)(A). Congress authorized the FDA to adopt standards regulating the level of any ingredient, including nicotine. *Id.* § 387g(a)(3). And to prevent potentially harmful tobacco products from saturating the market before regulators could catch up, the Act requires premarket FDA review of new tobacco products. *Id.* § 387j.

Third, the Act reinstated a modified version of a 1996 rule restricting tobacco industry marketing practices to children and adolescents. *Id.* § 387a-1(a). For cigarettes and smokeless tobacco, the reinstated rule bans the sponsorship of concerts and athletic events in the name of a tobacco brand, and bars the distribution of merchandise bearing a tobacco brand name or logo. 21 C.F.R. § 1140.34(a), (c). And for all tobacco products

subject to Chapter IX of the Food, Drug, and Cosmetic Act, the rule generally bans the distribution of free samples. Pub. L. No. 111-31, § 102(a)(2)(G); 21 C.F.R. § 1140.16(d).

C. The FDA's regulatory authority

Congress made the Tobacco Control Act applicable to four categories of tobacco products — "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco" — as well as "to any other tobacco products that the Secretary [of Health and Human Services] by regulation deems to be subject to this subchapter." 21 U.S.C. § 387a(b).

Congress authorized the HHS Secretary to issue regulations implementing the Federal Food, Drug, and Cosmetic Act, *id.* § 371(a), including to deem tobacco products subject to oversight, *id*. § 387a(b). The Secretary executes these duties "through the Commissioner" of Food and Drugs, *id*. § 393(d)(2), to whom the Secretary has delegated rulemaking authority for over 50 years. 29 Fed. Reg. 471 (Jan. 18, 1964).

Congress also gave the HHS Secretary broad authority to appoint subordinates to help carry out the agency's mission. In addition to the general power to hire employees consistent with congressional appropriations, 5 U.S.C. § 3101, the HHS Secretary also has the power to appoint senior executives to Senior Executive Service (SES) positions allotted by the Office of Personnel Management. *Id.* §§ 3131, 3133. SES members are "highly competent senior executives" who are protected against removal on certain specified grounds but who remain "accountable and responsible for the effectiveness and productivity of employees under them." *Id.* § 3131; *see also id*. § 2302(b). And while the HHS Secretary and the FDA Commissioner are "responsible for ... establishing and implementing general policies respecting the management and operation of [FDA] programs and activities" and "coordinating and overseeing the operation of all

administrative entities" within the agency, 21 U.S.C. § 393(d)(2), Congress allowed the Secretary to delegate that authority to subordinates. 42 U.S.C. § 3501 (Sec. 6); 5 U.S.C. § 302(b).

Under the delegations of authority in effect when the deeming rule was issued, the HHS Secretary had delegated the authority to issue FDA regulations to the FDA Commissioner. FDA Staff Manual Guides § 1410.10(1)(A)(14) (Nov. 17, 2015) (APP 20). The HHS Secretary had authorized the Commissioner to redelegate that power, *id*., although the Secretary had reserved the authority to act on regulations presenting "highly significant public issues," FDA Staff Manual Guides § 1410.10(2)(A)(2) (APP 27, 38). Any FDA regulations that constitute "significant regulatory actions" also had to be reviewed by the Administrator of the Office of Information and Regulatory Affairs (OIRA). Exec. Order No. 12,866 § 6(b), 58 Fed. Reg. 51,735 (Sept. 30, 1993).

The FDA Commissioner, in turn, had redelegated the authority to sign FDA rules to the Associate Commissioner for Policy, an SES position.[3] FDA Staff Manual Guides § 1410.21(1)(G)(1) (July 5, 2012) (APP 43); U.S. Government Policy and Supporting Positions at v–vi, 70, Senate Committee on Homeland Security and Government Affairs (Dec. 1, 2016). That authority could not be further redelegated, *id*., and the Commissioner reserved the power to continue to exercise it. FDA Staff Manual Guides § 1410.21(1)(A) (APP 40); *see also* 21 C.F.R. § 10.25(b); *id*. § 10.33(a). That authority

[3] The position of Associate Commissioner for Policy was previously called the Assistant Commissioner for Policy and was renamed as part of an agency reorganization, as reflected in the agency's updated delegations of authority. APP 131; *see also* FDA Staff Manual Guides § 1410.21(1)(G)(1) (July 5, 2012) (APP 43); FDA Staff Manual Guides § 1410.21(1)(G)(1) (Sept. 21, 2016) (APP 52); U.S. Government Policy and Supporting Positions at 67, House Committee on Oversight and Government Reform (Dec. 1, 2012).

could also be rescinded by the Commissioner and the HHS Secretary. FDA Staff Manual Guides § 1410.10(1)(A)(14) (APP 19–20); FDA Staff Manual Guides § 1410.21(1)(A) (APP 40).

Like other SES positions in the FDA, the Associate Commissioner for Policy could be reassigned by the FDA Commissioner, subject to the concurrence of the HHS Secretary. FDA Staff Manual Guides § 1431.23(1)(C) (Mar. 8, 2005) (APP 59); *see also* 5 U.S.C. § 3131(5); *id.* § 3395(a)(1). The FDA Deputy Commissioner for Policy, another SES position, had the delegated authority to remove the Associate Commissioner for Policy from the SES entirely and to take other adverse actions against her, although the HHS Secretary could rescind that delegation. FDA Staff Manual Guides § 1431.23(1)(H)(3) (APP 60).

Then-HHS Secretary Kathleen Sebelius appointed Leslie Kux to the SES in 2012, where she served first as Assistant Commissioner for Policy and later as Associate Commissioner for Policy. APP 229, 230.

D. The FDA studies the risks of e-cigarettes

The FDA's statutory rulemaking authority includes the power to issue regulations "deem[ing]" "any other tobacco products" to be subject to the Tobacco Control Act. 21 U.S.C. § 387a(b). The Act "broadly defines tobacco products as extending to '*any* product made *or derived from* tobacco,'" *Sottera, Inc. v. FDA*, 627 F.3d 891, 897 (D.C. Cir. 2010) (quoting 21 U.S.C. § 321(rr)(1)), "including any component, part, or accessory of a tobacco product," 21 U.S.C. § 321(rr)(1). In 2010, the D.C. Circuit held that e-cigarettes meet this definition and thus that "the FDA has authority under the Tobacco [Control] Act to regulate electronic cigarettes, enabling it to mitigate or perhaps extinguish any harm to public health." *Sottera*, 627 F.3d at 899; *see also*

LLC v. FDA, 266 F. Supp. 3d 360, 381 (D.D.C. 2017) (holding that the "FDA [also] has the statutory authority to regulate open-system vaping devices"), *appeal pending on other grounds*, No. 17-5196 (D.C. Cir. argued Sept. 11, 2018). After extensive study, the FDA exercised its authority to regulate e-cigarettes in 2016. The record before the agency showed that e-cigarette use had recently spiked, especially among minors, and raised significant public health concerns.

E-cigarettes appeared in China in the early 2000s and were available in the United States by 2007. 81 Fed. Reg. 28,974, 28,978 (May 10, 2016); Hajek et al. (2014) at 1801 (AR 22,954). The earliest devices were "cig-alikes," so named for their resemblance to conventional cigarettes. *Id*. Later variations on this design came to be known as "vaping" devices. Despite some design variations, cig-alikes and vaping devices generally share three basic parts: a cartridge of liquid typically containing nicotine ("e-liquid"), an atomizer with a heating element, and a battery and other electronics. *Sottera*, 627 F.3d at 893. When a user sucks on the device, the atomizer vaporizes the e-liquid, which is inhaled as an aerosol. *Id*. Together, they are often generically referred to as e-cigarettes or — reflecting their primary function — electronic nicotine delivery systems (ENDS). *See, e.g.*, Surgeon General's Report (2014) at 752 (AR 15,336); 81 Fed. Reg. at 28,976.

E-cigarette use in the United States was negligible in the 2000s but has risen dramatically in recent years. 81 Fed. Reg. at 29,028–29,029. Current use (meaning use in the previous 30 days) by adults more than doubled (1.4% to 3.7%) from 2012 to 2014. *See* Zhu et al. (2013) at 3 (AR 23,871); Schoenborn & Gindi (2015) at 2 (AR 15,666). This spike is even more pronounced among youth: current use by high school students rose 8-fold (1.5% to 13.4%) from 2011 to 2014. 81 Fed. Reg. at 28,984. By 2014, e-cigarettes

had eclipsed conventional cigarettes as the most widely used tobacco product among youth, with more than 2.4 million current users in middle and high school alone. *Id.*

The e-cigarette market has ballooned in tandem, with domestic sales surpassing $3 billion in 2015. AR 23,950. E-cigarettes are sold alongside conventional cigarettes in supermarkets, pharmacies, convenience stores, and "big box" retailers, as well as online and in 5,000 to 10,000 "vape shops" across the country. Jonathan Adler et al., *Baptists, Bootleggers & E-Cigarettes*, 33 Yale J. Reg. 313, 336–339 (2016); Grana et al. (2013) at 72 (AR 21,015); AR 23,980–23,981. All told, at the time of the deeming rule, some 640–800 different e-cigarette devices (or 800–1,000 unique packaging configurations) were being sold in the United States, AR 23,987–23,989 — most of them imported from China, Grana et al. (2014) at 1972 (AR 15,582).

In contrast to conventional cigarettes, which are permitted in only two characterizing flavors (tobacco and menthol), e-liquid was sold in the United States in 4,000–8,000 different varieties (5,000–10,000 unique packaging configurations) at the time of the deeming rule. RIA 76–78. Many of these were fruit or candy flavored, magnifying "their appeal to youth and young adults." 81 Fed. Reg. at 29,011; *see, e.g.*, Grana & Ling (2014) at 400 (AR 23,128).

This explosion in virtually unregulated products raises significant public health concerns. Although the FDA recognized that completely switching to e-cigarettes could reduce the risk of tobacco-related disease for people currently smoking conventional cigarettes — one of the deadliest products ever brought to market — it found that e-cigarettes still pose significant health and safety risks, 81 Fed. Reg. at 29,047:

1. **Addictiveness of Nicotine:** Nicotine is "one of the most addictive substances used by humans," *id.* at 28,988, and "a powerful pharmacologic agent that acts in the brain and throughout

the body," Surgeon General's Report (1988) at 14 (AR 1183). "[N]icotine is psychoactive ('mood altering') and can provide pleasurable effects," and "causes physical dependence characterized by a withdrawal syndrome that usually accompanies nicotine abstinence." *Id.* E-cigarettes can deliver as much nicotine as conventional cigarettes — sometimes more. 81 Fed. Reg. at 29,031.

2. **Health Hazards of Nicotine:** Nicotine is toxic at high doses, and can harm adolescents, pregnant women, and fetuses. *Id.* at 29,033. Nicotine exposure during pregnancy "contribut[es] to multiple adverse outcomes, such as pre-term delivery and stillbirth," and "has lasting consequences for [fetal] brain development." Surgeon General's Report (2014) at 126 (AR 14,708). Nicotine exposure during adolescence "may have lasting adverse consequences for brain development." *Id.* Ingesting or touching e-liquids can cause nicotine poisoning, which can be fatal. 81 Fed. Reg. at 29,032 (1,700 e-liquid exposures reported to U.S. poison control centers from 2010–2013, mostly involving young children); *id.* at 29,036 (toddler died after ingesting liquid nicotine).

3. **Health Hazards of Other Ingredients:** Although most manufacturers do not disclose their ingredients, what information is available about the ingredients in e-liquids shows that many present health concerns. *Id.* at 29,029 (study found that 74% of e-liquids contained substances posing known inhalation risks); *id.* (study found that many e-liquids contain chemicals that can cause respiratory irritation and airway constriction, including at over double the recommended workplace safety limit); *id.* (study found that some e-liquids contain chemical that is highly toxic to human cells in lab tests); Hutzler et al. (2014) at 1295 (AR 22,703) (toxic compound used in antifreeze was found in many e-liquids).

4. **Variability in Content and Concentration:** Among e-liquids, there is "significant ... variability between labeled content and concentration and actual content and concentration." 81 Fed. Reg. at 28,984; *id.* at 29,034 (study found that some e-liquids claiming to be nicotine-free actually had high levels of nicotine); *id.* (study found that actual nicotine level of 65% of e-liquids deviated by more than 10% from concentration printed on labels).

5. **Variability in Nicotine Delivery:** Among e-cigarette devices, variations in design and performance affect the amount of chemicals actually inhaled by users. Nicotine delivery "varies widely depending on product characteristics, user puffing behavior[,] and nicotine solution concentration, leaving smokers unaware of the nicotine levels they are receiving." *Id.* at 29,032; Hajek et al. (2014) at 3 (AR 22,956). Devices that "heat[] e-liquids to higher

temperatures ... may result in nicotine delivery that is actually higher than that of a conventional cigarette." 81 Fed. Reg. at 29,031.

6. **Variability in Delivery of Other Toxic Chemicals:** Design variations affect the delivery of other toxic chemicals. The solvents in e-liquids are chosen to create aerosols simulating conventional cigarette smoke, but when vaporized at certain voltages, they can produce some of the same harmful byproducts as conventional cigarettes, sometimes at higher levels. Cheng (2014) at ii13 (AR 23,072). Devices operated at higher voltages deliver more formaldehyde, a known carcinogen, than conventional cigarettes. 81 Fed. Reg. at 29,031. Toxic heavy metals, silicates, and other compounds can also be transferred from e-cigarette parts into the inhaled aerosol. Williams et al. (2013) at 5 (AR 6977); 81 Fed. Reg. at 29,015.

7. **Risks of Batteries:** The batteries and other components in e-cigarettes pose health and safety risks. Serious injuries like facial burns and lost teeth have been attributed to exploding batteries. 81 Fed. Reg. at 29,035. The U.S. Fire Administration found that the shape of e-cigarettes makes them more likely to shoot off like "flaming rockets" when a battery fails. U.S. Fire Administration, Electronic Cigarette Fires and Explosions, at 1 (Oct. 2014) (25 media reports of e-cigarette explosions or fires from 2009–2014), *available at* https://www.usfa.fema.gov/downloads/pdf/publications/electronic_cigarettes.pdf. The U.S. Department of Transportation banned e-cigarettes from checked luggage after fires at Boston Logan and LAX showed that they "can overheat and cause fires when the heating element is accidentally activated or turned on." 80 Fed. Reg. 66,817, 66,817–66,818 (Oct. 30, 2015).

8. **Health Hazards to Nonusers:** E-cigarettes, like conventional cigarettes, may harm nonusers. Secondhand aerosol contains nicotine, which is absorbed through passive exposure, "with one study showing levels comparable to passive smokers" of conventional cigarettes. Grana et al. (2013) at 2 (AR 20,945); 81 Fed. Reg. at 29,031–29,032 (studies show that "secondhand e-cigarette aerosols have been found to contain at least 10 chemicals known to cause cancer, birth defects, or other reproductive harm").

9. **Marketing to Youth:** E-cigarette advertising specifically targets youth, mimicking the strategies once used by "Big Tobacco" and thus banned for conventional cigarettes. In addition to using flavors attractive to youth, e-cigarette companies air ads during programs with high youth viewership, like the Super Bowl, the Academy Awards, and on ESPN and Comedy Central. Durbin et al. (2014) at 16 (AR 18,686). These ads often use celebrity endorsements and depict e-cigarettes as glamorous, rebellious, sexy, and masculine.

> *Id*. at 17 (AR 18,688); Grana & Ling (2014) at 399 (AR 23,127). E-cigarette companies also sponsor and provide free samples at events geared toward youth, like concerts, music festivals, parties, and sporting events. Durbin et al. (2014) at 10 (AR 18,681).

The FDA recognized that it is unclear whether e-cigarettes might help some smokers quit, as the plaintiffs postulate. Although there is "some indication that such products may have the potential to help some individual users to quit using combusted tobacco products or to reduce their use of such products," "other evidence is to the contrary," and "some systematic reviews of available evidence indicate that there is currently insufficient data to draw a conclusion about the efficacy of e-cigarettes as a cessation device." 81 Fed. Reg. at 29,037. Indeed, e-cigarettes may actually *inhibit* quitting conventional cigarettes, as "adult smokers who begin to use e-cigarettes seldom completely quit combustible products," Primack et al. (2015) at 1019 (AR 23,907) — a particularly troubling prospect given the substantial risks of even light or intermittent smoking. As the Surgeon General has reported, "the strongest determinant of risk for many diseases (e.g., lung cancer) caused by tobacco use is the *duration*" — not the *quantity* — "of smoking." Surgeon General's Report (2010) at 78 (AR 1891). The U.S. Preventive Services Task Force, an independent, volunteer panel of national experts in prevention and evidence-based medicine, has concluded "that available data on the use of [e-cigarettes] for smoking cessation are quite limited and suggest no benefit among smokers intending to quit." AR 23,694.

The FDA also recognized that the extent to which e-cigarettes are a "gateway" to the use of other tobacco products, like conventional cigarettes, is uncertain as well. One study found that, despite the recent rise in youth e-cigarette use, "in aggregate, there was no change in overall current tobacco use among middle and high school students."

81 Fed. Reg. at 28,984–29,985. At the same time, there is evidence suggesting that "youth may initiate tobacco use with [e-cigarettes], become addicted [to nicotine], and then dual use or move on to traditional tobacco products." *Id.* at 29,040; *id.* at 29,040–29,041 (one-year study of initially nonsmoking youth and young adults showed that 68.8% of e-cigarette users progressed toward smoking (i.e., either tried conventional cigarettes or indicated that they might), compared to just 18.9% of nonusers); Primack et al. (2015) at 1018 (AR 23,906). This data is consistent with progression patterns seen with other tobacco products. 79 Fed. Reg. 23,142, 23,159 (Apr. 25, 2014).

While these competing hypotheses are the subject of further research, the FDA concluded that the known risks posed by e-cigarettes warrant regulation now. As the agency explained, even if e-cigarettes were ultimately proven to be a net benefit to public health, regulation of those products would benefit public health even further. 81 Fed. Reg. at 28,984.

E. The FDA issues a rule signed by Associate Commissioner for Policy Leslie Kux deeming e-cigarettes subject to the Act

In 2014, the FDA published a proposed rule in the Federal Register that would subject e-cigarettes (among other tobacco products) to regulation under the Tobacco Control Act. 79 Fed. Reg. at 23,142. The proposed rule was signed by then-Assistant Commissioner for Policy Leslie Kux. 79 Fed. Reg. at 23,207. She also signed a notice extending the comment period on the proposed rule. 79 Fed. Reg. 35,711 (June 24, 2014) (AR 11861–11862).

During the 105-day comment period on the proposed deeming rule, the agency received over 135,000 comments, including from one of the plaintiffs here. AR 125,272–

125,274 (Rave Salon d/b/a Joosie Vapes). None challenged Ms. Kux's authority to sign the proposed or final rule.

The FDA published the final deeming rule in the Federal Register in May 2016. 81 Fed. Reg. at 28,974. Like the proposed rule, the final rule was signed by Associate Commissioner Kux. *Id.* at 29,106.

The final rule deems e-cigarettes (among other tobacco products) subject to the Tobacco Control Act. *Id.* at 28,975. In addition, for "covered tobacco products" — generally including newly deemed products like e-cigarettes — the FDA exercised its authority to regulate distribution, marketing, and labeling in two ways. 21 U.S.C. § 387f(d)(1)–(2). First, to reduce youth access, the rule bans sales to those under age 18, requires identification checks of purchasers age 26 and under, and bars vending-machine sales except in adult-only facilities. 21 C.F.R. § 1140.14(b)(1)–(3). Second, to help consumers better understand the implications of using these products, the rule requires packages and advertisements of cigarette tobacco, roll-your-own tobacco, and covered tobacco products other than cigars to state: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." 21 C.F.R. § 1143.3(a)–(b). This warning must generally occupy 30% of the two principal display panels on packages and 20% of ads. *Id*.

F. Two FDA Commissioners ratify the deeming rule

After the final deeming rule was issued in May 2016, it was ratified by two different FDA Commissioners who were nominated by the President and confirmed by the Senate.

First, then-FDA Commissioner Robert M. Califf ratified the agency's prior actions in September 2016 as part of a broader agency reorganization: "I hereby ratify and

affirm any actions taken by you or your subordinate(s), which in effect involved the exercise of the authorities delegated herein prior to the effective date of this delegation." APP 144. That ratification included Associate Commissioner Kux's issuance of the deeming rule in May 2016, which she had done pursuant to a previous delegation authorizing her to sign FDA rules. FDA Staff Manual Guides § 1410.21(1)(G)(1) (July 5, 2012) (APP 43).

Second, then-FDA Commissioner Scott Gottlieb specifically ratified the deeming rule in April 2019:

> I hereby affirm and ratify the Deeming Rule as of the date it was published in the Federal Register on May 10, 2016, including all regulatory analysis certifications contained therein. I undertake this action based on my careful review of the rule, my knowledge of its provisions, and my close involvement in policy matters relating to this rule and its implementation, as well as its public health importance.

APP 231 (April 3, 2019).

G. The plaintiffs bring these cases challenging the deeming rule under the Appointments Clause

The plaintiffs — who include e-cigarette manufacturers and retailers — filed these three cases in 2018 challenging the deeming rule under the Appointments Clause of the Constitution (art. II, § 2, cl. 2) and the First Amendment. Compl. ¶¶ 49–57, ECF No. 1 (*Moose Joose*); Compl. ¶¶ 49–58, ECF No. 11-3 (*Rave Salon*); Compl. ¶¶ 62–71, ECF No. 11-1 (*Hoban*). After transfer to this Court, the cases were consolidated. Minute Order, Mar. 1, 2019. Briefing on the First Amendment claim has been stayed pending the D.C. Circuit's resolution of *Nicopure Labs, LLC v. FDA*, No. 17-5196. Minute Order, June 8, 2018.

III. Legal Standard

In cases challenging agency rules based on an administrative record, summary judgment "serves as a mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record." *Associated Dog Clubs of N.Y. State, Inc. v. Vilsack*, 75 F. Supp. 3d 83, 89 (D.D.C. 2014) (Cooper, J.) (citation omitted). Instead of applying the Federal Rule of Civil Procedure 56(a) standard, courts "determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Id.* (citation omitted).

IV. Argument

A. The Appointments Clause challenge has been forfeited because it was not raised during the rulemaking proceedings

The plaintiffs forfeited their Appointments Clause claim by failing to raise it in their rulemaking comments. "It is well established that issues not raised in comments before the agency are waived and this Court will not consider them." *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002). That principle applies with full force to Appointments Clause claims, which are "nonjurisdictional" and thus subject to "normal forfeiture rule[s]." *Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 574 F.3d 748, 755–756 (D.C. Cir. 2009) (per curiam) (*Intercollegiate I*). Courts therefore require — on pain of forfeiture — that plaintiffs first make a "timely challenge" to the "validity of [the] appointment" with the agency. *Lucia v. SEC*, 138 S. Ct. 2044, 2055 (2018); *accord In re DBC*, 545 F.3d 1373, 1377–1378 (Fed. Cir. 2008) (plaintiff waived Appointments Clause challenge to agency decision by failing to raise the issue with the agency); *Teamsters Local Union No. 455 v. NLRB*, 765 F.3d 1198, 1201 (10th Cir. 2014) (Gorsuch, J.) (same); *Kanabi & Co. v. SEC*, 733 F. App'x 918, 919 (9th Cir. 2018) (same).

Here, the plaintiffs had an opportunity to raise their Appointments Clause challenge with the FDA during the rulemaking process. Under their theory, the purported infirmity was apparent as soon as the FDA published the proposed deeming rule signed by Associate Commissioner Kux. 79 Fed. Reg. at 23,207; Pls.' Br. at 36 n.28, ECF No. 26 ("Because ACP Kux issued the notice of proposed rulemaking that triggered the earlier comment period, that action is also void under the Appointments Clause."). Yet neither the plaintiffs nor anyone else submitted a comment questioning her authority to sign the proposed or final rule.

This conclusion is not altered by *Estes v. U.S. Department of Treasury*, 219 F. Supp. 3d 17 (D.D.C. 2016) (Cooper, J.). Although that case held that the Appointments Clause challenge was not waived for failure to raise it during the rulemaking period, it did so on the ground that "the promulgating official's identity ... was only announced with the Rule's issuance," so the plaintiffs "had no way to raise [the] argument until the [agency] issued its final rule." *Id.* at 37 (final alteration in original). Here, Associate Commissioner Kux signed not only the final deeming rule, but also the proposed deeming rule, a notice extending the comment period, and hundreds of other FDA rules, as the plaintiffs acknowledge. Pls.' Br. at 16–17; *see also* Angela C. Erickson & Thomas Berry, *But Who Rules the Rulemakers?: A Study of Illegally Issued Regulations at HHS*, Pacific Legal Foundation Apr. 29, 2019, at 3, available at https://pd.pacificlegal.org/HHSReport ("Among FDA final rules [issued from 2001 through 2017], 98% were issued by career employees who have no constitutional authority to do so."); *id.* at 25 (reporting that Ms. Kux signed 385 rules since 2001). Indeed, the plaintiffs purport to foresee the same alleged defect in future FDA rules. Pls.'

Br. at 38, 40. The plaintiffs here thus had fair notice as to who would likely sign the final deeming rule.

Allowing the plaintiffs to raise their Appointments Clause challenge for the first time before this Court would be unfair to the agency. By failing to raise that challenge during the rulemaking process, the plaintiffs deprived the FDA of an opportunity to address the issue before promulgating the final rule. The loss of that opportunity was especially prejudicial because, according to the plaintiffs, it was the only time to address the issue — in their view, the purported defect could not be cured by the Commissioner's later ratification of the rule. Pls.' Br. at 29–40. Now, two years later, they seek to invalidate the entire rule — even though their challenge goes only to the identity of the person who signed the rule, not "the very power of the [agency] to act" in this area. *Noel Canning v. NLRB*, 705 F.3d 490, 497 (D.C. Cir. 2013), *aff'd*, 573 U.S. 513 (2014). They should not be permitted to sit on their hands at the allegedly critical time and object only after it is supposedly too late to fix the issue.

B. Ratification of the deeming rule has cured any defect

1. The deeming rule has been ratified by two FDA Commissioners whose appointment and authority are undisputed

Even if not forfeited, any Appointments Clause problem with the deeming rule was cured when either of two FDA Commissioners subsequently ratified it. The D.C. Circuit has "repeatedly held that a properly appointed official's ratification of an allegedly improper official's prior action ... resolves" an Appointments Clause claim "on the merits by 'remedy[ing] [the] defect' (if any) from the initial appointment." *Guedes v. ATF*, 920 F.3d 1, 13 (D.C. Cir. 2019) (brackets in original) (quoting *Wilkes-Barre Hosp. Co. v. NLRB*, 857 F.3d 364, 371 (D.C. Cir. 2017)).

Here, then-Commissioner Califf ratified the agency's prior actions in September 2016, which included Associate Commissioner Kux's signing of the deeming rule in May 2016: "I hereby ratify and affirm any actions taken by you or your subordinate(s), which in effect involved the exercise of the authorities delegated herein prior to the effective date of this delegation." APP 144. And then-Commissioner Gottlieb specifically ratified the deeming rule in April 2019: "I hereby affirm and ratify the Deeming Rule as of the date it was published in the Federal Register on May 10, 2016." APP 231. The plaintiffs do not question the appointment or authority of Commissioners Califf or Gottlieb, both of whom were nominated by the President and confirmed by the Senate. *See* 21 U.S.C. § 393(d)(1). Either of those two ratifications of the deeming rule conclusively resolves the plaintiffs' Appointments Clause claim here.

Ratification cures an Appointments Clause violation unless the plaintiff can show any "'continuing prejudice' from the violation." *Wilkes-Barre Hosp.*, 857 F.3d at 372 (quoting *FEC v. Legi-Tech, Inc.*, 75 F.3d 704, 708–709 (D.C. Cir. 1996)). That prejudice standard is effectively the same as the APA's "harmless error" rule, under which the burden is on the plaintiff, as the party asserting error — not the government, contrary to the plaintiffs' contention. *Guedes*, 920 F.3d at 13; *Combat Veterans for Cong. Political Action Comm. v. FEC*, 795 F.3d 151, 156–157 (D.C. Cir. 2015) (cited in *Guedes*, 920 F.3d at 13). The plaintiff must show that, but for the improperly appointed decisionmaker's decision, the properly appointed decisionmaker would have reached a different result. *Guedes*, 920 F.3d at 13; *Legi-Tech*, 75 F.3d at 709. Under that standard, agency ratifications are to be "take[n] ... at face value" — even those that might seem to be "nothing more than a 'rubberstamp'" of the prior decision. *See Legi-Tech*, 75 F.3d at 709; *accord Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 796 F.3d 111, 118

(D.C. Cir. 2015) (*Intercollegiate III*); *Wilkes-Barre Hosp.*, 857 F.3d at 372; *Andrade v. Regnery*, 824 F.2d 1253, 1257 (D.C. Cir. 1987) (no Appointments Clause violation even though ratifying official had been in office only three days and program in question had been extensively planned by his improperly appointed predecessor).

The plaintiffs have not met that standard here. They have identified no evidence suggesting that either Commissioner's ratification of the deeming rule was in any way influenced by the mere fact that Associate Commissioner Kux had previously signed it — let alone that, had she not signed it, either Commissioner would have issued a different rule. Commissioner Gottlieb's reasons for ratifying the deeming rule include his "careful review of the rule," his "knowledge of its provisions," his "close involvement in policy matters relating to this rule and its implementation," and the rule's "public health importance" — not the fact that Associate Commissioner Kux had previously signed it. APP 231. Both Commissioners' explanations readily satisfy the minimal standard for effective ratification.

The plaintiffs contend that, for ratification to be effective, the agency must show that it is "virtually inconceivable" that the outcome would be different under a properly appointed decisionmaker. Pls.' Br. at 30 (quoting *Legi-Tech*, 75 F.3d at 708). But *Legi-Tech* did not purport to announce a new "virtually inconceivable" standard; instead, it used that phrase in the course of explaining why the familiar "prejudice" standard was not met. 75 F.3d at 708; *accord Wilkes-Barre Hosp.*, 857 F.3d at 372 (ratification was effective because plaintiff failed to show any "'continuing prejudice' from the violation") (quoting *Legi-Tech*, 75 F.3d at 708–709). That prejudice standard is likewise not met here.

2. The subsequent studies do not render the ratifications ineffective

The plaintiffs challenge the effectiveness of Commissioner Gottlieb's April 2019 ratification, contending that it failed to account for studies released after the deeming rule's issuance in May 2016 supposedly showing that e-cigarettes are not as dangerous as previously thought. Pls.' Br. at 29–40. Notably, however, the plaintiffs do not address the earlier ratification in September 2016 by Commissioner Califf, which preceded nearly all of those studies. The Court can therefore resolve the plaintiffs' Appointments Clause claim based on that September 2016 ratification alone.

In any event, the later studies identified by the plaintiffs — which, as explained below, reported results similar to earlier studies considered by the FDA — do not diminish the effectiveness of Commissioner Gottlieb's April 2019 ratification. The relevant inquiry is whether Commissioner Gottlieb would have issued the rule *even if Associate Commissioner Kux had not signed it* — the alleged Appointments Clause violation. Ratification is effective as long as it corrects any "prejudice left over *from the allegedly invalid appointment*." *Guedes*, 920 F.3d at 13 (emphasis added); *accord Wilkes-Barre Hosp.*, 857 F.3d at 372 (ratification was effective because plaintiff "failed to assert any 'continuing prejudice' *from the violation*") (emphasis added; citation omitted). Under this standard, "the only relevant prejudice" is "the likelihood that the outcome was affected *by the Appointments Clause violation*." *State Nat'l Bank of Big Spring v. Lew*, 197 F. Supp. 3d 177, 185 (D.D.C. 2016) (emphasis added); *see also Legi-Tech*, 75 F.3d at 708–709 (ratification was effective because properly appointed decisionmakers were not "'influenced' by the unconstitutional presence of the [improperly appointed decisionmakers]"). Any failure to consider subsequent studies

has nothing to do with the alleged Appointments Clause violation here, which occurred (if at all) when the deeming rule was signed by Associate Commissioner Kux. "There is no Appointments Clause problem in limiting [a party] to the evidence ... submitted to the [allegedly improperly appointed decisionmaker]." *Intercollegiate III*, 796 F.3d at 122.

The plaintiffs' concern about the subsequent studies is not an Appointments Clause issue, but an Administrative Procedure Act issue: In essence, they contend that the agency's failure to revisit the deeming rule in light of those studies is arbitrary and capricious in violation of the APA. Pls.' Br. at 35–37. But the APA sets forth the proper procedure for addressing that concern. The plaintiffs can present those studies to the agency in a petition for rulemaking, *see* 5 U.S.C. § 553(e), and if dissatisfied with the agency's response, can challenge it in federal court, *see id.* §§ 702, 706. They cannot, however, raise that concern in the first instance in federal court before raising it with the agency itself. *See Auer v. Robbins*, 519 U.S. 452, 458–459 (1997). Doing so would impermissibly second-guess the agency's expert judgment based on extra-record evidence that was never submitted to the agency.[4] *See Camp v. Pitts*, 411 U.S. 138, 142

[4] Neither case cited by the plaintiffs is to the contrary. There were no Appointments Clause or ratification issues in *Butte County v. Hogen*, 613 F.3d 190 (D.C. Cir. 2010). Instead, that case held that it violated the APA for an agency to ignore information properly submitted to it before it made its final decision. *Id.* at 194–195. Here, the plaintiffs assert only an Appointments Clause claim, not an APA claim. And even if the plaintiffs asserted an APA challenge to the agency's failure to revisit the deeming rule, they never presented the intervening studies to the agency before Commissioner Gottlieb ratified the rule — unlike in Butte County. It cannot be arbitrary and capricious for Commissioner Gottlieb to have failed to consider studies never presented to him.

In *FEC v. NRA Political Victory Fund*, the ratification was ineffective because it occurred after a jurisdictional deadline for taking the action in question. 513 U.S. 88, 98–99 (1994). Here, by contrast, there was no jurisdictional deadline for the FDA to

(1973) ("The focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.").

Under the plaintiffs' theory, notwithstanding the two ratifications of the deeming rule, the agency would have to repeat the full-blown notice-and-comment rulemaking procedures — a result that "would do nothing but give [the plaintiffs] the benefit of delay." *See Wilkes-Barre Hosp.*, 857 F.3d at 372. But the D.C. Circuit has repeatedly rejected the argument that "ratification can only be effective if it involves a repetition of the procedures initially followed." *State Nat'l Bank of Big Spring*, 197 F. Supp. 3d at 184 (citing cases); *accord Alfa Int'l Seafood v. Ross*, 264 F. Supp. 3d 23, 46 (D.D.C. 2017) (ratification of rule was effective even though it was not published in Federal Register). Ratification does not require "a review of similar scope ... to ensure the absence of an Appointments Clause problem." *Intercollegiate III*, 796 F.3d at 123 n.5. Instead, it is effective as long as "a properly appointed official has the power to conduct an independent evaluation of the merits and does so." *Id.* at 117.

In all events, even if the later studies were relevant to the Appointments Clause issue, they would not establish the prejudice necessary to invalidate the ratification. The subsequent studies identified by the plaintiffs reported similar information as earlier studies presented to and considered by the FDA in 2016. *See, e.g.*, 81 Fed. Reg. at 29,037 (noting "some indication that [e-cigarettes] may have the potential to help some individual users to quit using combusted tobacco products or to reduce their use of such

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issue the deeming rule. As the D.C. Circuit has recognized, "if, in NRA, there had been no time limit ... the Court presumably would have come out the other way." *Doolin Sec. Sav. Bank, F.S.B. v. Office of Thrift Supervision*, 139 F.3d 203, 213 (D.C. Cir. 1998), superseded by statute on other grounds, Federal Vacancies Reform Act of 1998, Pub. L. No. 105-277, 122 Stat. 2681.

products," but observing that "other evidence is to the contrary"); *id.* at 29,040–29,041. The FDA provided a reasoned explanation for why, notwithstanding those earlier studies, it decided to adopt the deeming rule: Even if e-cigarettes were ultimately proven to provide a net benefit to public health (as the plaintiffs claim these later studies now show), it does not follow that they should be left entirely unregulated, as the plaintiffs urge; instead, regulation of the indisputable known risks of those products would benefit public health even further. *Id.* at 28,984. Indeed, the HHS Secretary and then-FDA Commissioner recently reaffirmed the FDA's commitment to regulating e-cigarettes on the ground that, although they might be an adult "off-ramp" from traditional cigarette use, "[i]t is crucial that e-cigarettes do not become an on-ramp for children to become addicted to nicotine." Azar & Gottlieb, *supra* n.1. The later studies identified by the plaintiffs thus provide no basis to conclude that the FDA would adopt a different rule today.[5]

[5] The plaintiffs also challenge the effectiveness of Commissioner Gottlieb's ratification on the ground that, after the deeming rule was finalized, the FDA issued guidance explaining that it intended to defer enforcement of certain provisions, supposedly showing that the agency would have incorporated those extended compliance dates into a new deeming rule. Pls.' Br. at 34–35. But that guidance simply modified a compliance policy announced in the preamble to the deeming rule, 81 Fed. Reg. at 29,004–29,006 & tables 2–3, *id.* at 29,010–29,012; it did not change the substance of the rule, *see id.* at 29,102–29,106 (adding or modifying 21 C.F.R. Parts 1100, 1140, and 1143), as the plaintiffs acknowledge, so it provides no basis to think that the FDA would issue a different rule today. Eliminating any doubt that those compliance-policy changes would not affect the deeming rule is the fact that the FDA announced those changes in industry guidance — not in a proposed rule — the most recent version of which was released almost simultaneous with Commissioner Gottlieb's ratification. In all events, perhaps the most significant of those compliance-policy changes has been vacated by another district court. *See Am. Acad. of Pediatrics v. FDA*, --- F. Supp. 3d ----, 2019 WL 2123397, at *26 (D. Md. May 15, 2019).

3. Ratification resolves any Appointments Clause defect on the merits, not on mootness grounds, so the voluntary cessation exception to mootness does not apply

The plaintiffs contend that even if ratification were effective, their Appointments Clause claim would still remain live under the "voluntary cessation of unlawful conduct" exception to the mootness doctrine. Pls.' Br. at 37–40. But the D.C. Circuit has "repeatedly held that a properly appointed official's ratification of an allegedly improper official's prior action, rather than mooting a claim, resolves the claim on the merits." *Guedes*, 920 F.3d at 13; *see also id.* at 12 ("ratification is generally treated as a disposition on the legal merits of the appointments challenge").

In any event, even if ratification were a mootness issue instead of a merits issue, the voluntary cessation exception would not apply. That exception keeps a case alive only when "the allegedly wrongful behavior [could] reasonably be expected to recur." *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 92 (2013). The exception thus does not apply when, by the time of suit, the official whose appointment is challenged "lack[s] the unilateral power, or the power at all, to voluntarily cease and restart the conduct complained of — having a[n unlawfully]-appointed [official] promulgate ... a rule adversely affecting" the plaintiffs. *Guedes*, 920 F.3d at 16. Here, two duly appointed FDA Commissioners have ratified the deeming rule, and Ms. Kux stepped down from the Associate Commissioner for Policy position in February 2019, so there is no reasonable likelihood that she will re-sign the deeming rule.[6] The voluntary cessation

[6] To the extent the plaintiffs contend that the Associate Commissioner for Policy might in the future sign some *other* rule adversely affecting them, their requested relief in this case — invalidation of the deeming rule — would not redress that injury as

exception therefore does not apply here. Either of the two ratifications is fatal to the plaintiffs' Appointments Clause claim.

C. The Appointments Clause claim fails on the merits because the deeming rule was issued by a duly appointed inferior officer

Even if not waived or cured by ratification, the plaintiffs' Appointments Clause claim would still fail on the merits because Associate Commissioner Kux was a duly appointed inferior officer.[7]

1. The Associate Commissioner for Policy is an inferior officer

The Appointments Clause provides the method for appointing "Officers of the United States," U.S. Const. art. II, § 2, cl. 2 — those officials who "exercis[e] significant authority pursuant to the laws of the United States." *Lucia*, 138 S. Ct. at 2051 (quoting *Buckley v. Valeo*, 424 U.S. 1, 126 (1976)). The appointment method differs depending on whether the officer is a "principal officer" or an "inferior officer." *Id.* at 2051 n.3. Principal officers must be nominated by the President and confirmed by the Senate, but Congress can authorize the appointment of inferior officers by the President alone, a court, or a department head — like the Secretary of Health and Human Services. U.S. Const. art. II, § 2, cl. 2; *Lucia*, 138 S. Ct. at 2051 n.3.

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required for Article III standing. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–561 (1992).

In any event, in recent practice, the Commissioner has signed proposed and final FDA rules. *See, e.g.*, 84 Fed. Reg. 12,740 (Apr. 2, 2019) (proposed rule); 84 Fed. Reg. 14,847 (Apr. 12. 2019) (final rule).

[7] The plaintiffs contend that rulemaking cannot be conducted by mere employees and instead must be done by officers. Pls.' Br. at 13–17. Because Associate Commissioner Kux was a duly appointed inferior officer, the Court need not decide whether employees can ever make rules without violating the Appointments Clause.

Contrary to the plaintiffs' contention, the Associate Commissioner for Policy is an inferior officer, not a principal officer. The "major differentiating feature" between principal and inferior officers is "the extent to which the officers are 'directed and supervised' by persons 'appointed by Presidential nomination with the advice and consent of the Senate.'" *Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 684 F.3d 1332, 1337 (D.C. Cir. 2012) (*Intercollegiate II*) (quoting *Edmond v. United States*, 520 U.S. 561, 663 (1997)). "Whether one is an 'inferior' officer depends on whether he has a superior." *Edmond*, 520 U.S. at 662. Inferior officers are thus "officers whose work is directed and supervised *at some level* by others" who were nominated by the President and confirmed by the Senate. *Id.* at 663 (emphasis added). Direction and supervision can be manifested through oversight of the officer, removal of the officer, and review of the officer's decisions.[8] *Id.* at 664–665; *Intercollegiate II*, 684 F.3d at 1338.

In analyzing the extent of direction and supervision, courts look to the superior's *ability* to direct and supervise — not whether the superior has in fact directed and supervised in any particular instance. *See Intercollegiate II*, 684 F.3d at 1341; *Estes*, 219 F. Supp. 3d at 38. Courts also consider not only the superior's authority to direct and supervise under *existing* law, but also the superior's power to *change* that law to regain more control; "a supervisor's ability to rescind provisions assuring an officer's independence can render that officer inferior." *In re Grand Jury Investigation*, 916 F.3d 1047, 1052 (D.C. Cir. 2019).

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[8] Besides direction and supervision, another less important factor distinguishing between principal and inferior officers is whether the office is limited in jurisdiction and tenure. *Morrison v. Olson*, 487 U.S. 654, 672 (1988); *Edmond*, 520 U.S. at 661–662.

Under this standard, the Associate Commissioner for Policy is an inferior officer, not a principal officer. Although the Associate Commissioner for Policy has the delegated authority to sign FDA regulations,[9] the FDA Commissioner (nominated by the President and confirmed by the Senate, 21 U.S.C. § 393(d)(1)) retains the power to "continue to exercise [that] delegated authority." FDA Staff Manual Guides § 1410.21(1)(A), (1)(G)(1) (APP 40, 43); *see also* 21 C.F.R. § 10.25(b); *id.* § 10.33(a). In addition to this supervision by the FDA Commissioner, the HHS Secretary (nominated by the President and confirmed by the Senate, 42 U.S.C. § 3501) also retains the authority to approve any FDA regulations presenting "highly significant public issues." FDA Staff Manual Guides § 1410.10(2)(A)(2) (APP 27, 38). Any regulations signed by the Associate Commissioner for Policy that constitute "significant regulatory actions" — including the deeming rule here — are also reviewed by the OIRA Administrator (nominated by the President and confirmed by the Senate, 44 U.S.C. § 3503(b)). Exec. Order No. 12,866 § 6(b), 58 Fed. Reg. 51,735; AR 28,886–29,460. And both the HHS Secretary and the FDA Commissioner can at any time rescind the Associate Commissioner for Policy's delegated rulemaking authority. FDA Staff Manual Guides § 1410.10(1)(A)(14) (APP 19–20); FDA Staff Manual Guides § 1410.21(1)(A) (APP 40).

The Associate Commissioner for Policy can also be removed from her position by officials nominated by the President and confirmed by the Senate. Specifically, the FDA Commissioner has the power to reassign the Associate Commissioner for Policy, subject

[9] The propriety of that delegation is not in question. "When a statute delegates authority to a federal officer or agency, subdelegation to a subordinate federal officer or agency is presumptively permissible absent affirmative evidence of a contrary congressional intent." *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 565 (D.C. Cir. 2004).

to the concurrence of the HHS Secretary. FDA Staff Manual Guides § 1431.23(1)(C) (APP 59); *see also* 5 U.S.C. § 3131(5); *id.* § 3395(a)(1). And although the FDA Deputy Commissioner for Policy (who is not nominated by the President and confirmed by the Senate) has the delegated authority to remove the Associate Commissioner for Policy from the Senior Executive Service entirely and to take other adverse actions against her, at any time the HHS Secretary can rescind that delegation and exercise that authority himself. FDA Staff Manual Guides § 1431.23(1)(H)(3) (APP 60). This direction, supervision, and removal authority make the Associate Commissioner for Policy an inferior officer.

The plaintiffs contend that the Associate Commissioner for Policy is a principal officer because she does not need advance approval to issue rules. Pls.' Br. at 19–20. But any rule issued by the Associate Commissioner for Policy can be reviewed by the FDA Commissioner under the Commissioner's retained rulemaking authority. FDA Staff Manual Guides § 1410.21(1)(A) (APP 40); 21 C.F.R. § 10.25(b); *id.* § 10.33(a). The most significant rules issued by the Associate Commissioner for Policy are also reviewed by the HHS Secretary and the OIRA Administrator before they go into effect. FDA Staff Manual Guides § 1410.10(2)(A)(2) (APP 38); Exec. Order No. 12,866 § 6(b), 58 Fed. Reg. 51,735. And the Associate Commissioner for Policy's delegated rulemaking authority can be rescinded at any time by the HHS Secretary and the FDA Commissioner. FDA Staff Manual Guides § 1410.10(1)(A)(14) (APP 19–20); FDA Staff Manual Guides § 1410.21(1)(A) (APP 40). Rules signed by the Associate Commissioner for Policy thus go into effect only because these other principal officers allow them to. *See Edmond*, 520 U.S. at 664–665 (fact that scope of control over officer is "not complete" does not make the officer a principal officer; what matters is that the officer

"ha[s] no power to render a final decision on behalf of the United States unless permitted to do so by other Executive officers").

The plaintiffs also contend that the statutory removal protections for the Associate Commissioner for Policy as a member of the Senior Executive Service make her a principal officer. Pls.' Br. at 20–21. But "when [C]ongress, by law, vests the appointment of inferior officers in the heads of departments, it may limit and restrict the power of removal as it deems best for the public interest." *United States v. Perkins*, 116 U.S. 483, 485 (1886); *accord Free Enterprise Fund v. Pub. Co. Accounting Oversight Bd.*, 561 U.S. 477, 493 (2010). The removal protections for the Associate Commissioner for Policy still allow substantial control. The SES statute lists particular prohibited grounds for removal, implicitly allowing removal for any other reason not listed — including, for example, failing to follow the direction and supervision of the FDA Commissioner or the HHS Secretary.[10] *See* 5 U.S.C. § 2302(b) (prohibiting removal on the basis of, inter alia, race, religion, sex, national origin, age, disability, marital status, or political affiliation). Also, any SES position — including the Associate Commissioner for Policy — can be excepted from the SES statutory removal protections to ensure adequate control. *Id.* §§ 2302(a)(2)(B), 3132(c), 3302, 7511(b). And "members of the Senior Executive Service may be reassigned or reviewed by agency heads," and thus do not "enjoy the same significant and unusual protections from Presidential oversight" as principal officers. *Free Enterprise Fund*, 561 U.S. at 506–507.

[10] The FDA Commissioner and HHS Secretary conduct an annual performance appraisal of the Associate Commissioner for Policy, and an unsatisfactory rating on that appraisal requires automatic reassignment, transfer, or removal from the SES. 5 U.S.C. § 4314(b)(3), (c)(3); FDA Staff Manual Guides § 1431.23(1)(B) (APP 59).

Indeed, the Associate Commissioner for Policy's removal limits are less protective than other removal limits the Supreme Court has approved for inferior officers. The Associate Commissioner for Policy, who can be removed for any reason except the particular grounds listed in the SES statute, is at least as susceptible to removal as the independent counsel in *Morrison*, who could be removed "only for" the particular reasons listed in the statute. 487 U.S. at 663 (allowing removal "only for good cause, physical disability, mental incapacity, or any other condition that substantially impairs the performance of [her] duties") (quoting 28 U.S.C. § 596(a)(1)). Yet the Supreme Court did not dwell on those removal limits in holding that the independent counsel "clearly f[ell] on the 'inferior officer' side of th[e] line." 487 U.S. at 671. Instead, the key fact there — and a fortiori here — was that she was "subject to removal by a higher Executive Branch official." *Id.*

Finally, the plaintiffs contend that the power to make agency rules is so significant that it necessarily makes the Associate Commissioner for Policy a principal officer. Pls.' Br. at 21–23. But "'[o]fficers,' both principal and inferior, have the power to issue rules." *Alfa Int'l Seafood*, 264 F. Supp. 3d at 41 (citing *Buckley*, 424 U.S. at 141). The plaintiffs' contention "confuses a question of supervision for one of authority." *Ass'n of Am. R.Rs. v. Dep't of Transp.*, 821 F.3d 19, 38 (D.C. Cir. 2016). The significance of an official's duties does not determine whether she is a principal officer or an inferior officer.[11] "The exercise of 'significant authority pursuant to the laws of the United States'

[11] Indeed, for two of the three executive departments created in 1789, Congress authorized the Secretary of those departments (himself a "principal officer") to appoint an "inferior officer" as his second-in-command. *See* Act of July 27, 1789, Sess. I, ch. 4, 1

marks, not the line between principal and inferior officer for Appointments Clause purposes, but rather ... the line between officer and nonofficer."[12] *Edmond*, 520 U.S. at 662 (quoting *Buckley*, 424 U.S. at 126); *accord Ass'n of Am. R.Rs.*, 821 F.3d at 38. Accordingly, in its two most recent principal-vs.-inferior officer cases, the Supreme Court, "once satisfied that the persons in question exercised significant authority and were thus officers, went on to discuss only direction and supervision," not significance of authority.[13] *Intercollegiate II*, 684 F.3d at 412 (citing *Edmond*, 520 U.S. at 662); *accord*

Stat. 28–29 (Department of Foreign Affairs); *id.*, ch. 7, 1 Stat. 49–50 (Department of War).

Consistent with this practice, the Supreme Court has held a variety of subordinate officials exercising significant power to be inferior officers, not principal officers. *See, e.g.*, *United States v. Eaton*, 169 U.S. 331, 343 (1898) (vice consul temporarily charged with consul's duties); *Ex parte Siebold*, 100 U.S. 371, 397–398 (1879) (election supervisor charged with overseeing local congressional elections); *Go-Bart Importing Co. v. United States*, 282 U.S. 344, 352–353 (1931) (United States commissioner with power to arrest and imprison for trial, issue warrants, and prosecute voting and civil rights cases); *Morrison*, 487 U.S. at 671–672 (independent counsel charged with investigating and prosecuting certain federal crimes); *Edmond*, 520 U.S. at 661–662 (judges of military court of criminal appeals charged with reviewing court-martial proceedings resulting in sentences up to and including death).

[12] As explained above (at p. 28 n.7), the Court need not decide whether rulemaking is such significant authority that it can never be done by non-officers because Associate Commissioner Kux was an inferior officer.

[13] For that reason, the plaintiffs' contention that "the D.C. Circuit has twice found agency rule-makers to be principal officers" is a red herring. Pls.' Br. at 18–19 (citing *Intercollegiate II*, 684 F.3d at 1335, and *Ass'n of Am. R.Rs.*, 821 F.3d at 36). What made the officials in those cases principal officers was not their power to make rules (or, more accurately, to adjudicate disputes), but their freedom from direction and supervision.

The judges in *Intercollegiate II* were thus principal officers because no other executive branch official could control or reverse their rate determinations. 684 F.3d at 1339–1340. Likewise, the arbitrator in *Association of American Railroads* was a principal officer because no one could review his decisions. 821 F.3d at 39. By contrast, all rules issued by the Associate Commissioner for Policy can be reviewed by the FDA Commissioner, and the most significant rules are also reviewed by the HHS Secretary and the OIRA Administrator. FDA Staff Manual Guides § 1410.21(1)(A) (APP 40); 21

Free Enterprise Fund, 561 U.S. at 510. As explained above, the substantial direction and supervision to which the Associate Commissioner for Policy is subject make her an inferior officer under the Appointments Clause, not a principal officer who must be nominated by the President and confirmed by the Senate.

2. Ms. Kux was duly appointed as Associate Commissioner for Policy

As an inferior officer, the Associate Commissioner for Policy can be appointed by a department head as provided by Congress. U.S. Const. art. II, § 2, cl. 2; *Lucia*, 138 S. Ct. at 2051 n.3. The Secretary of Health and Human Services is one of the department heads within the meaning of the Appointments Clause. *See* 5 U.S.C. § 101 (the "Executive departments" include the Department of Health and Human Services); 42 U.S.C. § 3501; *Free Enterprise Fund*, 561 U.S. at 510–511; *Freytag v. Commissioner*, 501 U.S. 868, 886 (1991).

The HHS Secretary appointed Ms. Kux to the Assistant Commissioner for Policy position (later renamed Associate Commissioner for Policy). Although the FDA Commissioner has the delegated authority to make Senior Executive Service appointments, that power is "subject to the concurrence of the Secretary."[14] FDA Staff

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C.F.R. § 10.25(b); *id.* § 10.33(a); FDA Staff Manual Guides § 1410.10(2)(A)(2) (APP 27, 38); Exec. Order No. 12,866 § 6(b), 58 Fed. Reg. 51,735.

Also, the judges in *Intercollegiate II* could be removed only for misconduct or neglect of duty, 684 F.3d at 1340, and the arbitrator in *Association of American Railroads* apparently could not be removed at all, 821 F.3d at 39 — unlike the Associate Commissioner for policy, who can be removed for any reason except the limited grounds listed in 5 U.S.C. § 2302.

[14] The plaintiffs contend that this concurrence power does not satisfy the Appointments Clause because it constrains the Secretary to a yes-or-no choice. Pls.' Br. at 26 n.11. But nothing in the FDA Staff Manual Guides limits the Secretary's involvement to a yes-or-no choice. The Secretary remains free to consult with the

Manual Guides § 1431.23(1)(B) (APP 59). Thus, when Ms. Kux was appointed to the SES, the Commissioner completed HHS Form 820, which is necessary "for all executive personnel actions requiring Departmental approval." APP 229. On that form, the Commissioner listed her "reason[s] for recommending [Ms. Kux's] selection" and noted her "[c]oncurrence" in the appointment, but the appointment was "[a]pproved" by the Secretary herself. APP 229. The Secretary also signed Ms. Kux's SES certificate. APP 230.

The Secretary was authorized by Congress to make that appointment. Congress has given the Secretary broad authority to appoint subordinates to help carry out the agency's mission: "The Secretary, through the Commissioner, shall be responsible for ... establishing and implementing general policies respecting the management and operation of programs and activities of the [FDA]" and "coordinating and overseeing the operation of all administrative entities" within the agency. 21 U.S.C. § 393(d)(2). Congress gave the Secretary the power to appoint senior executives to SES positions allotted by the Office of Personnel Management. 5 U.S.C. §§ 3131, 3133. And Congress allowed the Secretary to delegate any function to agency subordinates. 42 U.S.C. § 3501 (Sec. 6); 5 U.S.C. § 302(b).

Commissioner about candidates for the position, and, if the Commissioner fails to select a satisfactory candidate, the Secretary can rescind the Commissioner's delegated appointment authority. Consistent with the Appointments Clause, the concurrence power ensures that no one can become Associate Commissioner for Policy without the Secretary's approval. *See United States v. Hartwell*, 73 U.S. 385, 393–394 (1867) (officer appointed by the assistant treasurer "with the approbation of the Secretary of the Treasury" was considered "appointed by the head of a department" consistent with Appointments Clause).

The plaintiffs contend that Ms. Kux was not properly appointed as an inferior officer because no statute specifically names the Associate Commissioner for Policy position. Pls.' Br. at 24–25. But courts have refused to impose an atextual gloss on the Appointments Clause requiring Congress to "specifically provide for the appointment of a particular inferior officer" in its grant of appointment authority. *Pa. Dep't of Pub. Welfare v. HHS*, 80 F.3d 796, 804–805 (3d Cir. 1996). The Supreme Court has noted, for example, that a statute authorizing the Transportation Secretary to "appoint and fix the pay of officers and employees of the Department of Transportation and ... prescribe their duties and powers" gave the Secretary the power to appoint Coast Guard judges, even though the statute did not "specifically mention" them. *Edmond*, 520 U.S. at 656; *see also In re Grand Jury Investigation*, 916 F.3d at 1053–54 (statutes authorizing the Attorney General "to appoint subordinate officers to assist him in the discharge of his duties" gave him the power to appoint a special counsel); *Willy v. Admin. Review Bd.*, 423 F.3d 483, 491–492 (5th Cir. 2005) ("The broad language employed by Congress in the Reorganization Plan No. 6 of 1950 and in 5 U.S.C. § 301 vests the Secretary [of Labor] with ample authority to create the [Administrative Review Board], appoint its members, and delegate final decision-making authority to them."); *Varnadore v. Sec'y of Labor*, 141 F.3d 625, 631 (6th Cir. 1998) (similar). Likewise, Congress's broad grant of authority to the HHS Secretary here satisfies the Appointments Clause.

Ms. Kux's appointment by a department head pursuant to congressional authorization thus makes her a duly appointed inferior officer under the Appointments Clause. A central aim of the Appointments Clause is to ensure accountability: "Without a clear and effective chain of command, the public cannot 'determine on whom the blame or the punishment of a pernicious measure ... ought really to fall.'"

Fund, 561 U.S. at 498 (quoting The Federalist No. 72, at 476 (J. Cooke ed. 1961) (A. Hamilton)). That principle is not at risk here. The deeming rule was issued by an inferior officer who was appointed by the HHS Secretary, who exercised authority delegated to her by the FDA Commissioner, and whose delegated authority could have been rescinded at any time. The rule has been repeatedly endorsed by Secretary and the Commissioner from its rollout to the present, and it was ratified by the only two Senate-confirmed Commissioners to serve in the years since, ensuring accountability. APP 225–226; Azar & Gottlieb, *supra* n.1; APP 144; APP 231.

V. Conclusion

The plaintiffs' motion should be denied and the government's cross-motion should be granted.

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Respectfully submitted,

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