IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

MOOSE JOOCE; MOUNTAIN VAPORS; RUSTIC VAPORS; and DUTCHMAN VAPORS, Plaintiffs, v. FOOD AND DRUG ADMINISTATION, et al., Defendants.	No. 1:18-cv-00203-CRC
RAVE SALON, INC., d/b/a JOOSIE VAPES, Plaintiff, v. FOOD AND DRUG ADMINISTRATION, et al., Defendants.	No. 1:18-cv-01615-CRC
JEN HOBAN d/b/a MASTERPIECE VAPORS, et al., Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, et al., Defendants.	No. 1:19-cv-00372-CRC

MOOSE JOOCE, ET AL.'s MOTION FOR PARTIAL SUMMARY JUDGMENT

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 7(h), Plaintiffs Moose Jooce, et al., move for partial summary judgment against Defendants Food and Drug Administration, et al., on Plaintiffs' Appointments Clause claim for relief.

The Administrative Procedure Act (APA) requires the Court to set aside agency action that is arbitrary, capricious, or not in accordance with law. 5 U.S.C. § 706(2)(A). Rules may only be issued by someone properly appointed as an officer of the United States. *Buckley v. Valeo*, 424 U.S. 1, 126, 140–41 (1976) (per curiam). Rules issued by career employees, whose hiring does not conform to the Appointments Clause, must be vacated. *Intercollegiate Broadcasting System, Inc. v. Copyright Royalty Bd.*, 684 F.3d 1332, 1342 (D.C. Cir. 2012). FDA's rule published on May 10, 2016, deeming "vaping" products to be subject to FDA's authority and the requirements of the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 28,973, violates the APA because it was issued by a career civil service employee who had not been properly appointed as an officer of the United States, and thus it was contrary to the Appointments Clause of the U.S. Constitution.

Plaintiffs' arguments are set forth in detail in the accompanying Memorandum of Points and Authorities, the Administrative Record certified by FDA, and the Declarations of Michael Wolberg, Kevin Price, Dennisa Moore, William S. Green, and Kimberly Manor.

The Court should enter summary judgment in Plaintiffs Moose Jooce, et al.'s favor; declare that the Deeming Rule was issued contrary to the Appointments Clause; and vacate and set aside the Deeming Rule.

A proposed Order is attached.

Dated: May 2, 2019.

Respectfully submitted,

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INTRODUCTION

Executive Branch rule-makers exert extraordinary authority over countless facets of American life. Long before the advent of the modern administrative state, the Framers understood that curbing abuses of such significant exercises of executive power requires the careful cabining of the prerogative to appoint those who wield that power.

They accordingly specified who must appoint officers exercising significant authority. *See* U.S. Const. art. 2, § 2, cl. 2. The President, with the advice and consent of the Senate, must appoint anyone who possesses the authority and independence of a principal officer. *See* U.S. Const. art. 2, § 2, cl. 2. Less powerful offices may be filled by someone appointed unilaterally by the President, a Court of Law, or the Head of a Department, but only if Congress first authorizes the appointment in that alternative manner. *See id*.

This constitutional requirement serves a fundamental purpose in democratic government. The Framers recognized that a diffuse appointment power would produce an army of officials who exist outside the chain of democratic accountability. The Appointments Clause ensures democratic accountability because "those who wield[] [the appointment power are] accountable to political force and the will of the people." *Freytag v. C.I.R.*, 501 U.S. 868, 883–84 (1991). *See Edmond v. United States*, 520 U.S. 651, 660 (1997) ("[T]he Appointments Clause was designed to ensure public accountability for both the making of a bad appointment and the rejection of a good one."). Therefore, only constitutionally appointed, principal officers—those who,

because of the means of their appointment, are most democratically accountable—may issue binding rules.

The danger that the Framers recognized has been realized in this case. The Deeming Rule, which has profound impacts on an entire industry of small businesses, was issued by a mere agency employee—the Associate Commissioner for Policy (ACP) Leslie Kux—who has been unconstitutionally given the powers and independence of a principal officer. *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, No. FDA-2014N-0189, 81 Fed. Reg. 28,973 (May 10, 2016) ("Deeming Rule" or "the Rule").

Despite occupying a position requiring appointment as a principal officer, ACP Kux was neither appointed by the President nor confirmed by the Senate. Congress has not authorized her appointment by other means nor, in any event, was she appointed by the President, a Court of Law, or the Head of a Department. Yet, ACP Kux purported to issue binding final rules under her own authority without any properly appointed officers taking responsibility for these actions. This practice breaks the Constitution's prescribed chain of political accountability. And, in fact, this practice is also the standard operating procedure for the Food and Drug Administration (FDA). The same employee issued approximately 400 final rules (about 98% of FDA rules issued during her tenure as ACP), touching the full spectrum of activities and industries regulated by FDA.

Because ACP Kux issued the Deeming Rule pursuant to the power and independence unconstitutionally granted to her as a mere agency employee, that rule is, and must be declared, *ultra vires*. The former FDA Commissioner's effort to ratify the rule on the eve of briefing cannot save the rule because that ratification is ineffective. A purported ratification of a rule issued in violation of the Appointments Clause is nugatory if, among other reasons, the rule would likely be different were the agency to start the rule-making process afresh untainted by the violation. Here, substantial evidence indicates that, were FDA to go back to the drawing board, any resulting rule would likely differ from the Deeming Rule illegally issued by ACP Kux.

Relatedly, the FDA Commissioner's ratification is invalid because it contains no explanation, much less a reasoned explanation, for why the Deeming Rule would be issued today in precisely the form that it was issued in 2016 despite the significant developments in the interim. Absent such evidence of reasoned decision-making, the purported ratification is arbitrary and capricious under the Administrative Procedure Act.

Finally, even if the FDA Commissioner's ratification is valid, the Court should still address the merits of Plaintiffs' Appointments Clause claim. A valid ratification of a rule challenged on Appointments Clause grounds normally moots such a challenge. But mootness does not bar a court's adjudication of the merits of a claim if the mootness is the result of the defendant's voluntary cessation of the challenged activity. Here, the FDA Commissioner has been a party to the litigation from day one. But the FDA Commissioner chose not to ratify the rule for more than a year after this

action was initiated, only two days before leaving office, and on the eve of briefing. Further, Commissioner Gottlieb failed to acknowledge the violation and take steps to prevent its recurrence, all of which underscores the propriety of applying the voluntary cessation exception here.

STATEMENT OF LAW AND FACTS

A. The Tobacco Control Act

Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) to address the "cancer, heart disease, and other serious adverse health effects" associated with use of "tobacco products" and other issues related to smoking and the use of cigarettes. Pub. L. No. 111–31, 123 Stat. 1776, 1777, § 2 (2009). Because of cigarettes' serious public health effects, the Tobacco Control Act's restrictions are strict and its remedies severe. Among other things, the Act: (i) makes it unlawful to market misbranded or adulterated tobacco products; (ii) requires manufacturers of tobacco products to submit detailed product and advertising information to FDA; (iii) requires manufacturers to register manufacturing facilities with FDA and open such facilities for biannual FDA inspections; (iv) authorizes FDA to impose restrictions on the sale and distribution of tobacco products, and to require warning labels for tobacco products; (v) authorizes FDA to regulate the methods used in manufacturing tobacco products; (vi) grants FDA authority to mandate new product safety standards regarding the composition and characteristics of tobacco products; (vii) directs tobacco product manufacturers to keep certain records; (viii) requires manufacturers to obtain advance FDA authorization before making

certain advertising and labeling claims; and (ix) grants FDA authority to promulgate testing requirements. 21 U.S.C. §§ 387a–387k, 387o, 387t.

B. The Associate Commissioner for Policy (ACP)

The Tobacco Control Act delegates to the Secretary of Health and Human Services authority to regulate the manufacture, marketing, and distribution of "tobacco product[s]," defined as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr)(1); 21 U.S.C. §§ 387a, 387a–1. The Secretary of Health and Human Services sub-delegated that rulemaking power to the FDA Commissioner. *See* 2016 FDA Staff Manual Guide § 1410.10(1)(A)(1) (Aug. 26, 2016), APP000029 (delegating all rulemaking authority under the Food, Drug, and Cosmetic Act, including the Tobacco Control Act). He, in turn, sub-sub-delegated this rulemaking power to the ACP. *See* 2016 FDA Staff Manual Guide § 1410.21(1)(G)(1) (Sept. 1, 2016), APP000052.

Pursuant to this sub-sub-delegation, the ACP's powers include the authority to issue "proposed and final regulations" under the Food, Drug, and Cosmetic Act, including any regulations under the Tobacco Control Act. *Id.* In fact, pursuant to these delegations, the ACP may unilaterally promulgate any rule within FDA's jurisdiction that she deems "necessary or appropriate." *See id.*; 21 C.F.R. § 10.40. The ACP may, on her own, determine whether a rule she issues requires a regulatory flexibility analysis. 2016 FDA Staff Manual Guide, *supra*, § 1410.21(1)(G)(4),

APP000053. And she may decide FDA's official response to a variety of petitions. 21 C.F.R. §§ 10.33, 10.35, 10.85.

Despite these authorities, ACP Kux was not appointed by the President with the advice and consent of the Senate. *See* Senate Committee on Homeland Security and Governmental Affairs, United States Government Policy and Supporting Positions 70 (2016) (hereinafter Plum Book) (noting that the ACP incumbent in 2016—ACP Kux—was not presidentially appointed). *See also id*. at vi (legend for interpreting the Plum Book). Nor was she appointed by the President, a Court of Law, or the Head of a Department. *See* Plum Book at 70. Instead, ACP Kux was an employee within the Career Senior Executive Service ("Career SES"). *See id. See also* U.S. Food and Drug Administration, "Meet Leslie Kux, Associate Commissioner for Policy" (last visited Apr. 30, 2019).[1] As a Career SES employee, ACP Kux was protected from removal except for "misconduct, neglect of duty, malfeasance, or failure to accept a directed reassignment or to accompany a position in a transfer of function." 5 U.S.C. § 7543. As a member of the Career SES, ACP Kux was selected by "[t]he Commissioner and the Deputy Commissioner [of FDA] . . . subject to the concurrence of the Secretary." 2005 FDA Staff Manual Guide § 1431.23(1)(B) (Mar. 8, 2005), APP000059.

[1] *Available at* https://www.fda.gov/AboutFDA/CentersOffices/ucm304642.htm.

C. The Deeming Rule's Issuance by ACP Kux

On May 10, 2016, ACP Kux issued the Deeming Rule. *See* Deeming Rule, 81 Fed. Reg. at 28,982 (citing statutory authority for issuance of the rule, including 21 U.S.C. §§ 371(a), 387a); *id.* at 29,016 (identifying ACP Leslie Kux as the sole issuer of the rule). The Rule purports to deem electronic nicotine delivery systems, such as vaping devices, to be tobacco products, thereby subjecting them to regulation under the Tobacco Control Act. 81 Fed. Reg. at 28,975.

In contrast to the traditional tobacco industry, the vaping industry comprises thousands of small, independent businesses. *See, e.g.*, 81 Fed. Reg. at 29,076 ("most [vaping] businesses are small"). Peer-reviewed studies have concluded that vaping is much safer than using cigarettes, because vaping does not generate the toxins associated with combusting and smoking tobacco.[2] Indeed, the Deeming Rule acknowledges studies that show: (i) vaping devices enable "substantial reductions in the exposure to harmful constituents typically associated with smoking" when "compared to cigarettes"; (ii) "most of the chemicals causing smoking-related disease from combusted tobacco use are absent" in the vapor generated by vaping devices;

[2] *See* David T. Levy, et al., *A Framework for Evaluating the Public Health Impact of E-Cigarettes and Other Vaporized Nicotine Products*, Soc'y for Study of Addiction 7 (Apr. 2016), www.onlinelibrary.wiley.com/doi/10.1111/add.13394/abstract ("The evidence suggests a strong potential for [vaping product] use to improve population health by reducing or displacing cigarette use in countries where cigarette prevalence is high and smokers are interested in quitting."); Tobacco Advisory Group of The Royal College of Physicians, *Nicotine Without Smoke: Tobacco Harm Reduction* 189 (Apr. 2016), www.rcplondon.ac.uk/file/3563 ("Large-scale substitution of e-cigarettes . . . for tobacco smoking has the potential to prevent almost all the harm from smoking in society.").

(iii) "the chemicals that are present" in vapor generated by vaping devices "pose limited danger"; and (iv) vaping devices "are likely to be much less, if at all, harmful to users or bystanders" than cigarettes. 81 Fed. Reg. at 29,030–31.

Yet, because of the Deeming Rule, these products are now subject to the Tobacco Control Act's requirements, including premarket approval, labeling, and advertising provisions. Manufacturers, distributors, and retailers are now prohibited from distributing "free samples" of vaping products. 81 Fed. Reg. at 29,054. They are also subject to restrictions on speech concerning "modified risk tobacco products," 81 Fed. Reg. at 29,005 (citing 21 U.S.C. § 387k), which means that they must seek and obtain FDA permission before informing consumers that their products are "free of a substance." Premarket review is required for all new vaping products, 81 Fed. Reg. 28,977, and existing products must undergo this review by August 8, 2022. *See* FDA, *Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (Revised)* (Mar. 2019).[3]

D. The Deeming Rule's Effects on the Plaintiffs

The plaintiffs in this case include a nonprofit organization devoted to improving public health by promoting tobacco harm reduction, several manufacturers of vaping products, and several retailers whose business activities and freedom of expression have been harmed by the Deeming Rule. *See* Green Decl. ¶¶ 6–8; Manor Decl. ¶¶ 6–10; Moore Decl. ¶¶ 6–8; Price Decl. ¶ 7; Wolberg Decl. ¶ 5.

[3] *Available at* https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf.

Tobacco Harm Reduction 4 Life, the nonprofit organization, seeks to reduce tobacco consumption through public education and advocacy of alternatives that offer reduced harms. Price Decl. ¶ 4. Because the Deeming Rule threatens one of the main harm-reduction alternatives, it has fundamentally changed the group's activities. *Id.* ¶ 7. Now, its resources are depleted by the need to rebut public misperceptions and address the regulatory consequences of FDA deeming these products to be tobacco products. *Id*. But for the Deeming Rule, these resources would be better spent on educating smokers about opportunities to avoid the harms of tobacco. *Id*. ¶¶ 8–9.

Several Plaintiffs manufacture their own line of vaping liquids. Manor Decl. ¶ 2; Moore Decl. ¶ 2 (explaining that Joosie Vapes blends e-liquids to produce their own flavors); Wolberg Decl. ¶ 2. As manufacturers under the Deeming Rule, they must submit any new products to FDA's pre-market approval process. Manor Decl. ¶ 10; Moore Decl. ¶ 6; Wolberg Decl. ¶ 6. For this reason, Plaintiffs have been unable to develop new products their clients want because FDA approval for these products would be prohibitively expensive. Moore Decl. ¶ 6; Wolberg Decl. ¶¶ 6–7, 9. Existing products will have to undergo this review soon, at which point many of the Plaintiffs will have to incur great cost or cease production. Manor Decl. ¶¶ 7–10; Moore Decl. ¶ 6.

In the meantime, they have had to change the labels on their products to accommodate the Deeming Rule's labeling requirements. Manor Decl. ¶¶ 8-9, 12; Moore Decl. ¶ 7. Moose Jooce, for instance, had to pull its products from the shelves for an entire year while it developed compliant labels. Manor Decl. ¶ 8. The Deeming Rule's required warnings take up 30% of their new label, which has caused them to have to remove their logo and truthful information useful to advertising their products. Manor Decl. ¶¶ 9, 12.

Some Plaintiffs previously assembled vaping devices for customers new to vaping. Green Decl. ¶ 10; Manor Decl. ¶ 6. This service gave them a competitive edge over online sellers and was extremely useful to new customers because an improperly assembled device could harm the user. Green Decl. ¶ 10. Because this service would cause some Plaintiffs to have to register as a manufacturer, they have had to discontinue it. Green Decl. ¶ 10. As a result, Plaintiffs have lost substantial business and have inventory they cannot sell because the devices are too complicated for customers to assemble without assistance. Green Decl ¶ 11.

Plaintiffs are also regulated as retailers. Moore Decl. ¶ 8. They can no longer offer free samples to customers new to vaping, limiting their ability to find the vaping liquid that best fits the customer's taste. Green Decl. ¶ 7; Wolberg Decl. ¶ 12. The number and variety of products they sell have been reduced, as the Deeming Rule has driven many companies out of business. Green Decl. ¶ 8.

These retailers also face significant speech restrictions. They cannot give customers truthful information, such as that their products do not contain certain

carcinogens commonly found in cigarette smoke or the relative health effects of vaping versus cigarettes. Green Decl. ¶ 13; Manor Decl. ¶ 12. For instance, Moose Jooce hangs a banner in its store quoting former FDA Commissioner Gottlieb's tweet that "I believe if every currently addicted adult smoker switched completely to e-cigs it would provide a tremendous public health gain." Manor Decl. ¶ 15. Yet this is not a statement that Kim Manor or Moose Jooce could make themselves. *Id*.

Plaintiffs must forego any speech that would even arguably violate the rule because of the strict penalties imposed. Green Decl. ¶¶ 14–15; Moore Decl. ¶¶ 8–9. For instance, Steve Green of Mountain Vapors cannot risk imprisonment or a large fine and thus his speech has been chilled. Green Decl. ¶ 15. He no longer tells his customers how he was a 2+ pack a day smoker for 35 years, had health problems because of it, and quit thanks to vaping. Green Decl. ¶¶ 3, 15.

All of these injuries are directly traceable to the Deeming Rule's application of the Tobacco Control Act to vaping products and devices. And all of these injuries would be redressed should the Deeming Rule be set aside.

STANDARD OF REVIEW

Summary judgment is proper when there is no genuine issue as to any material fact. Fed. R. Civ. P. 56(c). It is the ordinary means for deciding cases brought under the Administrative Procedure Act. *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006); *see* 5 U.S.C. § 706(2)(A) (requiring courts to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law"). Whether a rule was

issued in violation of the Appointments Clause is a pure question of law that is appropriate for resolution by summary judgment. *See, e.g.*, *Estes v. U.S. Dep't of the Treasury*, 219 F. Supp. 3d 17, 38–39 (D.D.C. 2016).

SUMMARY OF ARGUMENT

The Deeming Rule is invalid because its issuer was a career employee who enjoyed power and independence that the Appointments Clause limits to those validly appointed under its procedures. The power to issue final rules is "significant authority pursuant to the laws of the United States" and thus can be exercised only by someone properly appointed as an officer of the United States. *See Buckley v. Valeo*, 424 U.S. 1, 126, 140–41 (1976) (per curiam). The Deeming Rule was issued not by a duly appointed officer, but a mere employee to whom a staff manual delegates ongoing authority to issue final regulations on behalf of the FDA. *See* 2016 FDA Staff Manual Guide, *supra*, § 1410.21(1)(G)(1), APP000052. Yet the power and independence enjoyed by the ACP prohibit a mere employee from occupying the position; instead, it may only be filled by a properly appointed principal officer. *See Edmond*, 520 U.S. at 663–65 (explaining that inferior officers enjoy limited authority and are directed and supervised by principal officers).

Defendants admit that ACP Kux was not appointed by the President with the advice and consent of the Senate. Defendants' Answer ¶ 34; *cf.* Plum Book at 70. Further, Congress has not authorized by law the ACP's unilateral appointment by the President, a Court of Law, or the Head of a Department. Therefore, even if this

position could be an inferior office, ACP Kux did not undergo the required appointment process.

Rules issued in violation of the Appointments Clause must be vacated. *See Intercollegiate Broadcasting System, Inc. v. Copyright Royalty Bd.*, 684 F.3d 1332, 1342 (D.C. Cir. 2012). Recognizing this, the outgoing FDA Commissioner purported to ratify the Deeming Rule on the eve of briefing. But this ratification is ineffective or otherwise stands as no obstacle to the Court's adjudication of the merits. Therefore, because ACP Leslie Kux issued the Deeming Rule while serving in violation of the Appointments Clause, that rule must be set aside.

ARGUMENT

I. The Issuance of the Deeming Rule by a Mere Employee, Rather Than an Officer of the United States, Violates the Appointments Clause

So long as the ACP possesses rulemaking power[4]—as was the case when ACP Kux issued the Deeming Rule[5]—it is a position that can be occupied only by a duly-

[4] Many Appointments Clause cases concern offices created by statute with a fixed constellation of powers. The ACP, however, was delegated power by the FDA Commissioner who may also reclaim that power, subject to the limits on employee reassignment. 5 U.S.C. § 2302(a)(2). Thus, if the Court agrees that ACP Kux's power and independence violated the Appointments Clause, the FDA Commissioner can decide whether to terminate the position, retain it with appropriately limited powers, or seek a proper appointment for its occupant.

[5] ACP Kux has left FDA and her former office is now occupied by ACP Lowell J. Schiller. *See, e.g.*, Listing of Color Additives Exempt From Certification; Synthetic Iron Oxide; Confirmation of Effective Date, 84 Fed. Reg. 16,205 (Apr. 18, 2019). ACP Schiller may also be serving in violation of the Appointments Clause, but this case depends solely on ACP Kux's status at the time that she issued the Deeming Rule. Therefore, this personnel change has no bearing on the merits of Plaintiffs' Appointments Clause claim.

appointed officer of the United States.[6] In fact, its powers and independence are so comprehensive that it can be occupied only by a principal officer appointed by the President with the advice and consent of the Senate. ACP Kux was not appointed in this manner. And even if this position could be filled by an inferior officer, ACP Kux was not appointed in the manner required for an inferior officer either. Instead, she was a mere employee who was never validly appointed to any office under the Appointments Clause, and thus was unconstitutionally exercising power reserved to properly appointed officers of the United States.

A. The ACP's Significant Authority Limits Those Who Can Occupy That Position to Duly Appointed Officers of the United States

"Two decisions set out [the Supreme] Court's basic framework for distinguishing between officers and employees." *Lucia v. S.E.C.*, 138 S. Ct. 2044, 2051 (2018). First, the Court has "made clear that an individual must occupy a 'continuing' position established by law to qualify as an officer." *Id.* at 2051 (quoting *United States v. Germaine*, 99 U.S. 508, 511 (1878)). *See Landry v. FDIC*, 204 F.3d 1125, 1133 (D.C. Cir. 2000) (noting that "the threshold trigger for the Appointments Clause" is that an office be "established by Law") (citations omitted). Second, an individual must "exercis[e] significant authority pursuant to the laws of the United States." *Buckley*, 424 U.S. at 126. The ACP met both requirements when ACP Kux issued the Deeming Rule.

[6] For ease of readability, this brief will use the present tense when referring to the powers and tenure protections held by the ACP. But each of these arguments will be in reference to the powers and tenure protections held by ACP Kux in May, 2016, when the Deeming Rule was issued.

1. The ACP Is a Continuing Position Established by Law

For an office to be "established by law" it need not be created by statute but may also be created by regulation or internal agency directives. *See United States v. Mouat*, 124 U.S. 303, 307–08 (1888) (including "regulations of the navy" in a list of laws that might have potentially established an officer position). After all, "it would seem anomalous if the Appointments Clause were inapplicable to positions extant in the bureaucratic hierarchy," and "assigned 'significant authority,' merely because neither Congress nor the executive branch had formally created the positions." *Tucker v. C.I.R.*, 676 F.3d 1129, 1133 (D.C. Cir. 2012) (citing, *inter alia*, Office of Legal Counsel, Officers of the United States Within the Meaning of the Appointments Clause, 31 Op. O.L.C. 73, 117 (2007)).

The ACP is a position established by law because FDA staff manual guides delegate significant authority to that position. *See* 2016 FDA Staff Manual Guide, *supra*, § 1410.21(1)(G) APP000052–53. It is also a continuing position because these guides place no temporal limitation on the delegation of this authority—sovereign authority is assigned and does not expire upon the passage of time or the completion of a discrete task. *See Auffmordt v. Hedden*, 137 U.S. 310, 327 (1890) (a position is "continuing" if its duties are "continuing and permanent, not occasional or temporary" (quoting *Germaine*, 99 U.S. at 510–11); *United States v. Hartwell*, 73 U.S. (6 Wall.) 385, 393 (1867)).

2. The ACP's Rulemaking Power Is Significant Authority

The ACP also meets the second, more fundamental requirement of officer status: it is a position the occupant of which "exercis[es] significant authority pursuant to the laws of the United States." *Buckley*, 424 U.S. at 126. The power to issue final and binding rules on behalf of the United States is a significant authority. *See id.* at 140–41 ("*[R]ulemaking*, advisory opinions, and determinations of eligibility . . . [each] represent[ ] the performance of a significant governmental duty exercised pursuant to a public law." (emphasis added)). *See also Officers of the U.S.*, 31 Op. O.L.C. at 88 ("Similarly included in delegated sovereign authority is power to issue regulations and authoritative legal opinions on behalf of the government . . . ."). This power "may therefore be exercised only by persons who are 'Officers of the United States.'" *Buckley*, 424 U.S. at 140–41. *See also I.N.S. v. Chadha*, 462 U.S. 919, 952 (1983) (an official exercises significant authority when she "alter[s] the legal rights, duties and relations of persons," whether private parties or government actors).

The ACP has been delegated full rulemaking authority under the Food, Drug, and Cosmetic Act, including the Tobacco Control Act. *See* 2016 FDA Staff Manual Guide, *supra*, § 1410.10(1)(A)(1), APP000029, APP000052 (authorizing the ACP to assume the FDA Commissioner's authority to issue "proposed and final regulations of the Food and Drug Administration"). It is pursuant to that authority that ACP Kux issued approximately 400 final regulations during her tenure, including the Deeming Rule. *See* 81 Fed. Reg. at 28,982 (citing statutory authority for issuance of the rule, including 21 U.S.C. §§ 371(a), 387a); 81 Fed. Reg. at 29,016 (identifying ACP Leslie

Kux as the sole issuer of the rule); *see also* Angela C. Erickson & Thomas Berry, *But Who Rules the Rulemakers?: A Study of Illegally Issued Regulations at HHS* at 25 and note 18 (Table 1) (Apr. 29, 2019) (finding that Kux issued 385 rules as ACP during the study period ending Jan. 20, 2018, and that Kux continued to issue additional FDA rules until early 2019). In fact, the ACP holds comprehensive authority to make both substantive and procedural determinations in support of her rulemaking authority. *See* 2016 FDA Staff Manual Guide, *supra*, § 1410.21, APP000049–58.[7] The ACP exercises "significant authority pursuant to the laws of the United States" and, therefore, is a position that can only be filled by a properly appointed officer.

B. The ACP Must Be Appointed as a Principal Officer

Although the Supreme Court has not "set forth an exclusive criterion for distinguishing between principal and inferior officers for Appointments Clause purposes," a principal officer connotes someone who exercises independent authority and discretion, whereas the label of "inferior officer" generally "connotes a relationship with some higher ranking officer or officers below the President." *Edmond*, 520 U.S. at 661–62. Consequently, the Court has held that "'inferior officers' are officers whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate" and,

[7] In analyzing whether ACP is an officer position, this Court must look beyond just the power ACP Kux wielded in issuing the Deeming Rule and examine *all* of the ACP's powers. *See Tucker*, 676 F.3d at 1132 ("In assessing [plaintiff's Appointments Clause] claim, we look not only to the authority that Appeals employees wielded in [plaintiff's] case but to *all* their duties, or at least those to which [plaintiff] calls attention.").

by implication, a principal officer is one who can act on her own authority, without the approval of a superior. *Id*. at 663.

The D.C. Circuit has identified three distinct factors that bear upon whether an officer is "directed and supervised" by a superior: (1) whether the work of the officer is subject to substantial oversight by others who are appointed by the President with the advice and consent of the Senate, (2) whether the officer is removable without cause, and (3) whether the officer's decisions are reversible or correctable by another officer or entity within the Executive Branch. *Intercollegiate Broadcasting*, 684 F.3d at 1338.

Applying these principles, the D.C. Circuit has twice found agency rule-makers to be principal officers. The first case, *Intercollegiate Broadcasting*, concerned three copyright royalty judges tasked with promulgating "determinations and adjustments of reasonable terms and rates of royalty payments" for music broadcasters. 684 F.3d at 1335 (internal quotations and citation omitted). These judges were officers because they exercised "significant ratemaking authority." *Id.* at 1336. And they were principal officers because they were not removable at will and their decisions were final for the Executive Branch. *Id.* at 1339–40.

In the second case, *Association of American Railroads*, the D.C. Circuit once again found a rule-maker to be a principal officer. The Passenger Rail Investment and Improvement Act, Pub. L. No. 110–432, 122 Stat. 4848 (2008), created a position of "arbitrator," who was selected to create "[a] final agency action, the promulgation of metrics and standards as though developed jointly by Amtrak and the [Federal

Railroad Administration]," whenever called upon to resolve an impasse between those two bodies. *Ass'n of Am. R.R. v. U.S. Dep't of Transp.*, 821 F.3d 19, 36, 39 (D.C. Cir. 2016). The statute did not provide any procedure to remove or replace an arbitrator once one was selected. *See* 49 U.S.C. § 24101 (note). Nor did it "provide any procedure by which the arbitrator's decision [was] reviewable by" another executive-branch official or body. *Association of American Railroads*, 821 F.3d at 39. Nor, finally, did the Act provide any procedure by which the decision-making process of the arbitrator would be subject to oversight. *Id.* Instead, the arbitrator was authorized to take "[a] final agency action, the promulgation of metrics and standards" that "would appear in the Federal Register." *Id.* at 39, 37 (citation omitted). Given these three facts, the arbitrator was held to be a principal officer. *Id.* at 39.

Applying those same factors here leads to the conclusion that an ACP with rulemaking powers is a position that must be occupied by a principal officer. First, the ACP exercises significant authority without substantial oversight from anyone appointed by the President. The ACP is unrestricted in its discretion to formulate policy and issue rules. *See* 2016 FDA Staff Manual Guide, *supra*, § 1410.21(1)(G)(1), APP000052. The ACP need not gain advance permission from a superior to issue a rule; the delegations of power to the ACP require no prior approval to carry out any of her assigned powers. *Id.*[8] This lack of prior review by a superior distinguishes the

[8] Many rules go through internal reviews for compliance with statutory or administrative policies, including a review of significant rules by the Office of

ACP from other rule-makers for whom "substantial oversight" has been found. *Compare Estes*, 219 F. Supp. 3d at 38 (a department directive provided "that regulations be submitted from policy officials to the Executive Secretary for review, accompanied by a 'memorandum [which] shall, at a minimum, fully, clearly, and succinctly . . . describe the regulation [and] explain the reason it is being issued'") (citation omitted) *with* 2016 Staff Manual Guide, *supra*, 1410.21, APP000052–53.

> Yet, when the Deeming Rule was issued, the ACP's power and independence were conferred on a mere employee who could not be removed except for cause. In fact, as an employee within the Career Senior Executive Service, ACP Kux enjoyed substantial removal protections. 5 U.S.C. §§ 7541–7543; *see id.* § 2302(a)(2) (substantially limiting conditions under which "a career appointee position in the Senior Executive Service" may be "transfer[red], or reassign[ed]"); *see also* Plum Book 70 (identifying the ACP as a career appointee position in the Senior Executive Service). Although such protections are appropriate to prevent politicization of career employees who exercise no significant policy or political discretion, rulemaking is the quintessential policy and political action. Tenure protection for ACP Kux insulates the ACP's rulemaking decisions from the Constitution's chain of democratic accountability—precisely what the Appointments Clause is intended to prevent.

Information and Regulatory Affairs. *See* E.O. 12866, 58 Fed. Reg. 51,735 (Sept. 30, 1993). But no matter how many people influence a rule, one official ultimately determines its content and whether to issue it and bind the public. That official issues the rule in his or her own name.

This factor distinguishes ACP Kux from other officers that have been found to be inferior. In *In re Grand Jury*, for instance, the D.C. Circuit concluded that Special Counsel Robert Mueller was a validly appointed inferior officer. 916 F.3d 1047 (D.C. Cir. 2019). Key to the Court's conclusion was that he "effectively serves at the pleasure of an Executive Branch officer who was appointed with the advice and consent of the Senate." *Id.* at 1052. That was not the case for ACP Kux, who enjoyed tenure protections as a Career SES employee. She could not be fired or her pay cut except for cause. 5 U.S.C. § 7543.

And, finally, the ACP's rulemaking decisions qualify as final agency action under the Administrative Procedure Act, 5 U.S.C. § 704; *cf. Philip Morris USA Inc. v. FDA*, 202 F. Supp. 3d 31, 46–48 (D.D.C. 2016) (FDA's "substantial equivalence" guidance document under the Tobacco Control Act qualifies as a final agency action). The ACP has the authority to issue final and binding rules that are published in the Federal Register. *See* 2016 FDA Staff Manual Guide, *supra*, § 1410.21(1)(G), APP000052–53; 21 C.F.R. §§ 10.33, 10.35, 10.40, 10.45(d). These rules are binding not only on the public but also on the Executive Branch. *See Nat'l Envtl. Dev. Ass'n's Clean Air Proj. v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014) ("It is 'axiomatic,' however, 'that an agency is bound by its own regulations.'" (quoting *Panhandle Eastern Pipe Line Co. v. FERC*, 613 F.2d 1120, 1135 (D.C. Cir. 1979))). Under the Constitution, such final agency actions must be the exclusive province of a principal officer. *Cf. Dep't of Transp. v. Ass'n of Am. R.R.*, 135 S. Ct. 1225, 1239 (2015) (Alito, J.,

concurring) ("[N]othing final should appear in the Federal Register unless a Presidential appointee has at least signed off on it.").

In addition, the ACP's rulemaking powers are wide-sweeping and significant. That an office holds such powers suggests that it is reserved to principal officers. *See Morrison v. Olson*, 487 U.S. 654, 671–72 (1988). The D.C. Circuit has recognized conflict over the weight that should be given to this factor. *Intercollegiate Broadcasting*, 684 F.3d at 1337. But, whatever weight is assigned, the ACP's powers easily meet the significance threshold suggesting (at least) that the position can only be occupied by a duly-appointed principal officer.

Since 2001, the FDA has issued at least 138 rules deemed to be "significant" for the purposes of Executive Order 12866.[9] *See* Erickson & Berry, *supra*, at 36 (Table C1) (peer-reviewed study of FDA's practice of having employees issue rules).[10] Of these, employees holding the position of ACP or its equivalent predecessor position issued at least 121 significant rules, 87% of FDA's significant rules and an average of

[9] A rule is deemed significant for the purposes of Executive Order 12866 if it has "an annual effect on the economy of $100 million or more," adversely affects one of several economic subcategories, interferes with another agency action, alters the budgetary impact of certain core programs, or raises novel legal or policy issues. *See* E.O. 12866, 58 Fed. Reg. 51735, § 3(f).

[10] This is a legislative fact for which judicial notice is inapposite. *See* Fed. R. Evid. 201. The fact pertains not to the evidentiary basis for nor the procedures used in issuing the Deeming Rule but, rather, to a policy concern that can inform the Court's resolution of the legal issues raised. *See Ass'n of Nat'l Advertisers, Inc. v. F.T.C.*, 627 F.2d 1151, 1161–62 (D.C. Cir. 1979) (discussing the differences between legislative facts and adjudicative facts). However, were judicial notice necessary, such notice would be proper because the fact could be confirmed from sources whose accuracy cannot be reasonably questioned, namely the pertinent Federal Register notices and the Plum Book (both government documents).

more than six significant rules per year. *Id.* Just the Deeming Rule alone has drastically altered the entire vaping industry. *See generally* Lauren H. Greenberg, *The "Deeming Rule": The FDA's Destruction of the Vaping Industry*, 83 Brook. L. Rev. 777 (2018).

The ACP's rulemaking power spans the entirety of the Food, Drug, and Cosmetic Act, its authority is final, and it enjoys substantial removal protection. Yet, as Defendants concede in their answer, ACP Kux did not receive the Presidential appointment and Senate confirmation required of principal officers. Defendants' Answer ¶ 34. Therefore, ACP Kux was not validly serving as a properly appointed principal officer at the time she issued the Deeming Rule.

C. Even If the ACP Were an Inferior Officer, ACP Kux Was Not Validly Appointed

"Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments." U.S. Const. art 2, § 2, cl. 2. For multiple independent reasons, ACP Kux's appointment did not satisfy this procedure either. First, Congress has not authorized any means of appointment of the ACP other than nomination by the President with the advice and consent of the Senate. Second, ACP Kux was not appointed by the President, a court, or the head of a department, which are the only constitutional alternative means to appoint an inferior officer.

1. Congress Has Not Authorized the ACP's Appointment in Any Manner Other Than Presidential Appointment With the Advice and Consent of the Senate

"The prescribed manner of appointment for principal officers is also the default manner of appointment for inferior officers." *Edmond,* 520 U.S. at 660. An inferior officer must be nominated by the President and confirmed by the Senate unless Congress explicitly authorizes appointment through one of the other constitutional means. U.S. Const. art 2, § 2, cl. 2.

Congress has vested the Secretary of Health and Human Services with the authority to appoint several types of inferior officers, but the ACP is not among them. Further, in contrast to other departments, no statute grants broad, department-wide appointment power to the Secretary of Health and Human Services. Instead, that Secretary has been given far narrower appointment powers. For example, 42 U.S.C. § 913, which is found in the chapter of the U.S. Code dealing with the Social Security Administration, states that "[t]he Secretary [of Health and Human Services] is authorized to appoint and fix the compensation of such officers and employees . . . as may be necessary for carrying out the functions of the Secretary *under this chapter*." (Emphasis added).

As 42 U.S.C. § 913 demonstrates, Congress knows how to explicitly grant the Secretary of Health and Human Services a broad appointment power pursuant to the inferior officer clause. Yet Congress has not given that Secretary a general appointment power for either the Department of Health and Human Services or the FDA. Nor has it granted that Secretary an appointment power for any officer

resembling the ACP. For that reason, Congress has not vested the ACP's appointment in the Secretary "by law." The "default rule" of the Appointments Clause therefore applies: even if ACP Kux were an inferior officer, the Constitution requires that she have been nominated by the President and confirmed by the Senate. As Defendants admit, she was not.

2. ACP Kux Was Not Appointed by the President, a Court of Law, or the Head of a Department

ACP Kux was appointed to her position by the FDA Commissioner or Deputy Commissioner. 2005 FDA Staff Manual Guide, *supra*, § 1431.23, APP000059; Form HHS–820, Leslie Kux (Feb. 29, 2012), APP000229. That hiring would not satisfy the constitutional requirements for the appointment of an inferior officer, even if Congress had set aside the default rule. Congress can only authorize the President, a court of law, or the head of a department to unilaterally appoint an inferior officer. The FDA Commissioner is none of these.

A "department" for purposes of the Appointments Clause is "a freestanding component of the Executive Branch, not subordinate to or contained within any other such component." *Free Enter. Fund v. Pub. Co. Accounting Oversight Bd. (PCAOB)*, 561 U.S. 477, 511 (2010); *see also Freytag*, 501 U.S. at 886 ("Accordingly, the term 'Heads of Departments' does not embrace inferior commissioners and bureau officers.") (quoting *Germaine*, 99 U.S. at 510–11 (quotation marks and alterations omitted)); *id.* at 917–22 (Scalia, J., concurring in part and concurring in the judgment). The FDA is not a department but an agency contained within the Department of Health and Human Services. *See* 21 U.S.C. § 393(a).

Thus, the only head of a department within the Department of Health and Human Services is the Secretary, who did not appoint ACP Kux. *See* 2005 FDA Staff Manual Guide, *supra*, § 1431.23, APP000059; Form HHS–820, Leslie Kux, *supra*, APP000229.[11] Therefore, even if the powers of the ACP could be constitutionally exercised by an inferior officer, the Deeming Rule must still fall because ACP Kux was not appointed to her position by the President, a court of law, or the head of a department, even if Congress had authorized an alternative means of appointment.

II. The Deeming Rule Must Be Vacated

A. ACP Kux's Role in Issuing the Deeming Rule Renders It *Ultra Vires*

Rules issued by persons serving in violation of the Appointments Clause must be vacated. *See Intercollegiate Broadcasting*, 684 F.3d at 1342 ("Because the Board's structure was unconstitutional at the time it issued its determination, we vacate and remand the [ratemaking] determination . . . ."); *cf. Lucia*, 138 S. Ct. at 2055 ("[T]he appropriate remedy for an adjudication tainted with an appointments violation is a

[11] FDA hiring protocols authorize the FDA Commissioner or Deputy Commissioner to appoint the ACP and other career appointees in the senior executive service with the concurrence of the Secretary of Health and Human Services. A concurrence is only a yes-or-no choice to approve the hiring of a single candidate selected by someone else. Such a constrained choice does not satisfy the Appointments Clause. *See* A.T. Akerman, Civil-Service Commission, 13 Op. Att'y Gen. 516, 520 (1871) ("[The] right [of Congress] to prescribe qualifications [for offices] is limited by the necessity of leaving scope for the judgment and will of the person or body in whom the Constitution vests the power of appointment."); *cf. Myers v. United States*, 272 U.S. 52, 128 (1926) (noting that statutory limitations on an appointment power cannot "so limit selection and so trench upon executive choice as to be in effect legislative designation").

new hearing before a properly appointed official." (quoting *Ryder v. United States,* 515 U.S. 177, 183, 188 (1995)) (internal quotation marks omitted)).

Thus, the delegation of rulemaking authority to ACP Kux and her exercise of that authority in issuing the Deeming Rule violated the Appointments Clause and the rule must be set aside. *See* Deeming Rule, 81 Fed. Reg. at 29,016. *See also* 2016 FDA Staff Manual Guide, *supra*, § 1410.21(1)(G)(1), APP000052; *see also* 21 C.F.R. § 10.40. At FDA, the signer of the rule signifies who made the final decision to issue it. Some final FDA rules are signed by either the FDA Commissioner, the Secretary of Health and Human Services, or both, to signify that those officers have issued the rule. *See, e.g.*, Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents, 75 Fed. Reg. 13,225–03, 13,232 (Mar. 19, 2010) (final FDA rule signed by FDA Commissioner Margaret Hamburg and HHS Secretary Kathleen Sebelius); Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628–01, 36,755 (June 22, 2011) (same). But the Deeming Rule is not one of these. Instead, it was issued under ACP Kux's authority alone. *See* 81 Fed. Reg. at 29,016.

Further, although the Court need not reach this question, ACP Kux's role in the Deeming Rule's issuance would violate the Appointments Clause *even* if that role fell short of issuing this particular rule. The Appointments Clause requires consideration of an office's full powers, not just the power exercised in a particular case. If an officer is improperly appointed, *all* of the acts taken by that officer are *ultra vires*—not just those acts that rise to the level of significant authority. *See*

Landry, 204 F.3d at 1131–32 ("[The Supreme] Court made plain that, had it not found the 'inferior officer' appointed in a constitutional way, it was ready to throw out the Tax Court's decision simply on the ground that [the judge] held what it viewed as clearly the powers of an 'inferior officer' (to make final decisions), even though the [judge] had not exercised any power to make final decision in [that] case." (citing *Freytag*, 501 U.S. 871–72 & n.2)).

The performance of any necessary step by someone serving in violation of the Appointments Clause "pollute[s] the rulemaking process[.]" *See Ass'n of Am. R.R.*, 821 F.3d at 37 n.6. Here, in addition to issuing the final Deeming Rule, ACP Kux also issued the notice of proposed rulemaking that triggered the public comment process (and oversaw that process). Thus, even if ACP Kux had performed only a mere ministerial function in the issuance of this rule—which she did not—the rule would still need to be set aside as unconstitutional.

B. The De Facto Officer Doctrine Is Inapplicable in Appointments Clause Challenges

"The *de facto* officer doctrine confers validity upon acts performed by a person acting under the color of official title even though it is later discovered that the legality of that person's appointment or election to office is deficient." *Ryder*, 515 U.S. at 180 (citation omitted). But that doctrine cannot be invoked here to save the validity of the Deeming Rule, because the de facto officer doctrine is inapplicable in Appointments Clause challenges. *Id.* Applying the doctrine "would create a disincentive to raise Appointments Clause challenges with respect to questionable judicial appointments." *Id.* at 183. In fact, it cannot apply to any "'basic constitutional

protections designed in part for the benefit of litigants.'" *Id.* at 182 (quoting *Glidden Co. v. Zdanok*, 370 U.S. 529, 536 (1962)).

C. Despite Commissioner Gottlieb's Purported Ratification, the Court Should Reach the Merits

On April 3, 2019, outgoing FDA Commissioner Scott Gottlieb purported to ratify the Deeming Rule. Ratification of Deeming Rule (Apr. 3, 2019), APP000231. However, this does not satisfy the requirements for ratification of a rule issued in violation of the Appointments Clause.

It is not "virtually inconceivable" that reinitiating the rulemaking process would affect the content of a new Deeming Rule. *See FEC v. Legi-Tech, Inc.*, 75 F.3d 704, 708 (D.C. Cir. 1996) (allowing ratification because "it is virtually inconceivable" that a new process would affect the outcome, as opposed to merely resulting in delay). The Deeming Rule's preamble itself recognizes that the rule was issued in the face of scientific uncertainty. *See, e.g.*, 81 Fed. Reg. at 29,010 (acknowledging "the uncertainty regarding the positive or negative impact on public health from [vaping] products"). A new rule would account for the substantial development of the science in the three years since the Deeming Rule was issued, as well as the de facto changes FDA has made to the Deeming Rule through guidance documents. Further, Commissioner Gottlieb's failure to address these developments and to provide a reasoned explanation for why they should be ignored renders the ratification arbitrary and capricious. *See Butte County, Cal. v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010).

Even if the purported ratification were effective, it would not moot this case. Unlike in past Appointments Clause cases, the violation here is not a one-off error but the agency's standard practice. Therefore, the voluntary cessation exception to mootness would apply—requiring the Court to reach the merits despite a valid ratification.

1. Developments Since the Deeming Rule Was Issued Show That It Is Not "Virtually Inconceivable" That Notice and Comment Could Affect the Content of a New Deeming Rule

The Administrative Procedure Act does not authorize officers to "ratify" rules or other agency actions that were taken contrary to law. Instead, this practice is an accommodation courts have developed for cases where ratification would cause no prejudice to the plaintiffs. *See Doolin Sec. Sav. Bank, F.S.B. v. Office of Thrift Supervision*, 139 F.3d 203, 212 (D.C. Cir. 1998) (analogizing ratification to the APA's "harmless error" rule codified in 5 U.S.C. § 706). *Cf. Oglala Sioux Tribe v. U.S. Nuclear Reg. Comm'n*, 896 F.3d 520 (D.C. Cir. 2018) ("The harmless error standard of the APA merely requires a showing of prejudice. That standard does not 'impose a . . . particularly onerous requirement.'" (quoting *Shinseki v. Sanders*, 556 U.S. 396, 410 (2009))). The government bears the burden of showing that letting it off the hook for its Appointments Clause violation will cause no prejudice to the plaintiff. Courts have found that burden to be satisfied where a new process would have no effect whatsoever on the final outcome—other than causing unnecessary delay. *See, e.g.*, *Doolin*, 139 F.3d at 214 ("We are also sure that redoing the administrative proceedings would bring about the same outcome . . . ."); *Legi-Tech*, 75 F.3d at 708 ("[I]t is virtually inconceivable that its decisions would differ in any way the second

time from that which occurred the first time."); *Alfa Int'l Seafood v. Ross*, No. 1:17-cv-00031, 2017 WL 3738397, at *2 (D.D.C. June 22, 2017) (an agency must convince the court that it "would re-promulgate the Rule in the same manner, even if it were required to re-start the notice and comment process").

In this case, that standard is not satisfied. Several changes since the Deeming Rule was issued make it plausible—in all likelihood, quite probable—that a new notice and comment process would lead to material differences in a properly issued Deeming Rule. This case is distinguishable from the precedents discussed above because the Deeming Rule's preamble itself admits that the rule was issued in the face of substantial scientific uncertainty. 81 Fed. Reg. at 29,010 (acknowledging "the uncertainty regarding the positive or negative impact on public health from [vaping] products"). A new notice and comment process would consider the scientific developments since the original rule was issued, which developments have reduced this uncertainty.[12]

For instance, the results of a large, randomized trial published in February found that vaping is nearly twice as effective as nicotine replacement products at helping smokers quit cigarettes. Peter Hajek, et al., *A Randomized Trial of E-*

[12] Because Commissioner Gottlieb promptly left the agency after purportedly ratifying the Deeming Rule, that new process would be before another official. Former Commissioner Gottlieb's ratification provides no evidence as to how his successor would review the public comments, much less does it suggest what a new Deeming Rule would look like. *Cf. State Nat'l Bank of Big Spring v. Lew*, 197 F. Supp. 3d 177, 185 (D.D.C. 2016) (accepting ratification where a properly appointed official ratified his pre-appointment actions and any new rulemaking process would be decided by the same individual).

Cigarettes versus Nicotine-Replacement Therapy, 380 New Eng. J. Med. 629 (2019).[13] Even the government has commented favorably on the study. National Cancer Institute, *UK Clinical Trial Compares E-cigarettes, Nicotine-Replacement Products for Smoking Cessation* (Mar. 8, 2019) (praising the study as "rigorous and well-conducted").[14] In fact, this study is one of six published since the Deeming Rule was issued finding that vaping is singularly effective at helping smokers quit. *See, e.g.*, Anne Buu, et al., *The Association Between E-cigarette Use Characteristics and Combustible Cigarette Consumption and Dependence Symptoms*, 84 Addictive Behaviors 69 (2018);[15] Ann McNeill, et al., *Evidence Review of E-Cigarettes and Heated Tobacco Products 2018*, Public Health England (2018);[16] Shu-Hong Zhu, et al., *E-cigarette Use and Associated Changes in Population Smoking Cessation: Evidence from US Current Population Surveys*, 2017 BMJ 358;[17] Emma Beard, et al., *Association Between Electronic Cigarette Use and Changes in Quit Attempts, Success of Quit Attempts, Use of Smoking Cessation Pharmacotherapy, and Use of Stop Smoking Services in England*, 2016 BMJ 354;[18] Yue-Lin Zhuang, et al., *Long-Term*

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[13] *Available at* https://www.nejm.org/doi/full/10.1056/NEJMoa1808779.

[14] *Available at* https://www.cancer.gov/news-events/cancer-currents-blog/2019/e-cigarettes-nrt-smoking-cessation-clinical-trial.

[15] *Available at* https://www.ncbi.nlm.nih.gov/pubmed/29627636.

[16] *Available at* https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf.

[17] *Available at* https://www.ncbi.nlm.nih.gov/pubmed/28747333.

[18] *Available at* https://www.ncbi.nlm.nih.gov/pubmed/27624188.

E-cigarette Use and Smoking Cessation: A Longitudinal Study with US Population, 25 Tobacco Control i90 (2016);[19] Jamie Hartmann-Boyce, et al., *Electronic Cigarettes for Smoking Cessation*, 2016 Cochrane Database of Systematic Reviews No. CD010216.[20]

Other studies that have explored the health effects of vaping versus cigarettes have determined that vaping reduces the concentration of carcinogens and other dangerous chemicals in the human body. *See, e.g.*, Maciej L. Goniewicz, et al., *Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes*, JAMA Network (2018);[21] David T. Levy, et al., *Potential Deaths Averted in USA by Replacing Cigarettes with E-cigarettes*, 27 Tobacco Control 18 (2018);[22] Lion Shahab, et al., *Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users*, 166 Annals of Internal Medicine 390 (2017);[23] Allison M. Glasser, *Overview of Electronic Nicotine Delivery Systems: A Systematic Review*, 52 Am. J. Preventive Med. e33 (2017).[24]

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[19] *Available at* https://www.ncbi.nlm.nih.gov/pubmed/27697953/.

[20] *Available at* https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub3/full.

[21] *Available at* https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2718096.

[22] *Available at* https://tobaccocontrol.bmj.com/content/27/1/18.citation-tools.

[23] *Available at* https://www.ncbi.nlm.nih.gov/pubmed/28166548.

[24] *Available at* https://www.ncbi.nlm.nih.gov/pubmed/27914771.

Still other studies have explored the effects of different strategies to address youth vaping, suggesting that regulations that have the effect of raising prices can perversely increase youth cigarette smoking. *See, e.g.*, Dhaval Dave, et al., *The effects of e-cigarette minimum legal sale age laws on youth substance use*, 28 Health Economics 419 (2019);[25] Michael F. Pesko & Casey Warman, *The Effect of Prices on Youth Cigarette and E-cigarette Use: Economic Substitutes or Complements?* (2017).[26]

The Court need not evaluate the merits of these studies and predict how a new rule issued after a notice-and-comment process addressing these developments might differ from the Deeming Rule. Rather, it is sufficient that these developments suggest that changes are possible, if not all but certain.

In fact, FDA's own actions since the Deeming Rule's issuance belie the assertion that a new Deeming Rule would be identical to ACP Kux's version. Since the Deeming Rule was issued, the agency has amended it seven times through regulatory guidance documents. *See* FDA, *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule* at 15 (Mar. 2019) (listing guidance documents that have amended the Deeming Rule).[27] To be sure, these guidance documents just change the compliance deadlines rather than the Deeming Rule's substantive requirements. But should a new Deeming Rule be issued, it is

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[25] *Available at* https://www.ncbi.nlm.nih.gov/pubmed/30648308.

[26] *Available at* http://economics.emory.edu/home/documents/Seminars%20Workshops/GHER-2017-Pesko.pdf.

[27] *Available at* https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf.

likely that the rule would incorporate these extended deadlines. That change would provide real security to the Plaintiffs, as the extensions to the Deeming Rule's compliance deadlines now appear only in nonbinding guidance documents, which by definition may be rescinded without notice or explanation. *Cf. Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199 (2015) (notice and comment is not required to void interpretive rules, despite the regulated public's reliance).

Finally, these developments and the passage of time render the purported ratification ineffective because Commissioner Gottlieb lacked the authority to issue the rule in the same form as when he purported to ratify it. "[I]t is essential that the party ratifying should be able not merely to do the act ratified at the time the act was done, *but also at the time the ratification was made*." *FEC v. NRA Political Victory Fund*, 513 U.S. 88, 98 (1994) (internal quotation marks and citation omitted, emphasis in original). Here, three years passed between the issuance of the Deeming Rule and the purported ratification, during which, as set forth above, there were significant developments bearing on the question. Commissioner Gottlieb therefore could not, consistent with the Administrative Procedure Act, issue the same rule in 2019 without any explanation as to why the new developments do not warrant a different regulatory approach.

It is in fact arbitrary and capricious for an agency official to take an action without considering all of the available evidence and explaining how such evidence affects or does not affect the decision reached. *Butte County v. Hogen*, 613 F.3d at 194. In *Hogen*, the plaintiff county challenged the Department of Interior's approval of an

Indian gaming operation. *Id*. at 191–92. In 2003, the National Indian Gaming Commission and Interior's Solicitor determined that the area on which the Indian casino would be built was eligible for gaming. *Id*. at 193. But in 2006, the county presented evidence to the Secretary of Interior challenging that conclusion. *Id*. Yet, in 2008, the Secretary adopted the Gaming Commission and Solicitor's determination and approved the gaming operation without addressing the county's new evidence. *Id*. The Secretary's decision was held to be arbitrary and capricious because it failed even to acknowledge the county's new evidence, and thus was not the product of reasoned decision-making. *Id*. at 195.

So too here. Despite the scientific and enforcement developments since 2016, Commissioner Gottlieb's purported ratification provides no basis for this Court to conclude that he fully considered these developments and that the ratification was the product of informed, reasoned decision-making.[28] The Court can only speculate, for instance, whether Commissioner Gottlieb considered the more recent studies showing vaping's benefits as a smoking-cessation aid and, if so, how he weighed that evidence. Similarly, the Court can only conjecture as to whether Commissioner Gottlieb reviewed the effects of three years of implementing the Deeming Rule. Those effects, which Plaintiffs and others would raise in a new public comment process, are

[28] Because ACP Kux issued the notice of proposed rulemaking that triggered the earlier comment period, that action is also void under the Appointments Clause. Thus, Commissioner Gottlieb not only purported to ratify the Deeming Rule despite these substantial developments but also despite the fact that there has never been a properly noticed public comment process. In these circumstances, ratification necessarily prejudices the Plaintiffs.

critical for evaluating the Deeming Rule's impact on prices, which impact may actually worsen the problem of youth smoking. Further, one cannot surmise from the ratification whether Commissioner Gottlieb considered the changes the agency has made through guidance or whether incorporating those changes into a new rule would avoid prejudice to the Plaintiffs.

2. Even If the Ratification Were Effective, the Voluntary Cessation Exception to Mootness Would Apply

Even if Commissioner Gottlieb's ratification were effective, this Court should still reach the merits of Plaintiffs' Appointments Clause claim. Ratification does not cure the underlying violation—someone serving in violation of the Appointments Clause has still issued the Deeming Rule. Instead, ratification purports to moot further consideration of that claim by showing that the same rule would be issued by a properly appointed officer, without that officer actually going through the process to cure the violation. *See EEOC v. First Citizens Bank of Billings*, 758 F.2d 397, 399–400 (9th Cir. 1985) ("This issue [of whether the Department of Labor is vested with authority to enforce Equal Pay Act violations] was rendered moot when Congress enacted Public Law 98–532, which ratified and affirmed as law each reorganization plan . . . transferring authority to the EEOC."). *Cf. Guedes v. Bureau of Alcohol, Tobacco, Firearms and Explosives*, 920 F.3d 1, 12-17 (D.C. Cir. 2019) (although stating that 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," nevertheless acknowledging that "all of our prior ratification cases dealt with appointments challenges that arose as defenses to

enforcement actions" as opposed to "an independent, pre-enforcement challenge to an agency rule," and going on to at least entertaining the propriety of employing a mootness analysis to the latter type of ratification).

This case satisfies the voluntary cessation exception to mootness. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000). When a defendant voluntarily cures the particular instance of harm that plaintiffs have challenged, courts should nonetheless proceed to the merits unless it is "'absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.'" *Id.* (quoting *United States v. Concentrated Phosphate Export Ass'n,* 393 U.S. 199, 203 (1968)). The government, as the party purporting to have ceased the challenged conduct, carries "[t]he heavy burden of persuading the court that the challenged conduct cannot reasonably be expected to start up again." *Id.* (internal quotation marks, alteration, and citation omitted).

Here, that burden cannot be carried for several reasons. First, Defendants cannot show that there is no reasonable chance that the Appointments Clause violation will recur. As Plaintiffs have shown, the violation in this case was not some one-off error but the agency's standard operating procedure—a procedure that continues to this day. *See* Erickson & Berry, *supra*, at 25 and note 18 (Table 1) (reporting that a large percentage of FDA rules are issued by persons serving in violation of the Appointments Clause); *see also* 84 Fed. Reg. 16,205 (regulation issued by ACP Kux's successor). Commissioner Gottlieb's purported ratification does not acknowledge the Appointments Clause violation and end this practice by, for

example, withdrawing rulemaking power from the ACP. Instead, it denies any implication that the agency's practice is unlawful. Ratification of Deeming Rule, *supra*, APP000231. The voluntary cessation doctrine is intended precisely for cases like this, where a party asserts the power to unilaterally terminate a suit against it while reserving the right "to return to his old ways[.]" *United States v. W.T. Grant Co.*, 345 U.S. 629, 632 (1953); *see Guedes*, 920 F.3d at 15–16.

Compare this case to the "peculiar circumstances" in *Guedes*, in which the D.C. Circuit declined to apply the voluntary-cessation doctrine. 920 F.3d at 15. There, an improperly appointed acting attorney general issued a rule later ratified by the attorney general, once he was properly nominated by the President and confirmed by the Senate. *Id.* at 9. The independent mooting acts of parties not before the court—the President and the Senate—made the risk of "party manipulation" extremely remote. *Id.* at 15–16. Nor could the parties before the court resume the Appointments Clause violation, as the properly appointed attorney general displaced the improperly appointed acting attorney general.

In this case, by contrast, the purported ratifier—the FDA Commissioner—has been a party to the case all along. And there has been no material change between when this case was filed and today which would prevent the Defendants from resuming that practice, even if it were temporarily discontinued in an effort to have this case dismissed.

Second, the Deeming Rule will likely not be FDA's final word on vaping. This can be seen from both the scientific developments discussed above as well as recent

actions by the agency. Before he left the agency, Commissioner Gottlieb referenced preliminary FDA data showing that youth vaping is rising sharply and that, if this continues, "we'll swiftly change course." *See* Press Release, FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use* (Sept. 12, 2018); [29] *see also* Letter to Kevin Burns, Chief Executive Officer, Juul Labs, Inc., from Scott Gottlieb, FDA Commissioner (Feb. 6, 2019) (asserting that vaping manufacturers have a "responsibility to take action to address the epidemic of youth use of their products").[30] Additionally, the agency has demanded that vaping companies turn over new research, which could be used to craft additional rules. *See* Letter to Ziad Rouag from Matthew R. Holman, Director, FDA Office of Science (Apr. 24, 2018).[31]

Plaintiffs will likely be harmed by any future vaping rule and the agency's consistent practice further shows that such a rule is likely to be issued in violation of the Appointments Clause. Given that the next FDA rule to affect the vaping industry is likely to suffer from the same legal defect as the Deeming Rule did upon its issuance—as the office of the ACP still retains plenary final rulemaking power—this Court should not allow the FDA to evade the Appointments Clause question at the heart of this case by selectively ratifying only those rules that are challenged in litigation, while continuing to issue many more without proper authority.

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[29] *Available at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use.

[30] *Available at* https://www.fda.gov/media/122588/download.

[31] *Available at* https://www.fda.gov/media/112339/download.

CONCLUSION

For the foregoing reasons, Plaintiffs are entitled to summary judgment on their Appointments Clause claim. The Deeming Rule should be vacated.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 2, 2019, I electronically transmitted the attached document to the Clerk of the Court using the ECF System for filing. Based on the records currently on file, the Clerk of the Court will transmit a Notice of Electronic Filing to the following ECF registrants:

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s/ Jonathan Wood
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