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

PLAINTIFFS' COMBINED OPPOSITION & REPLY ON CROSS-MOTIONS FOR PARTIAL SUMMARY JUDGMENT

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Introduction

Plaintiffs Moose Jooce, *et al*., challenge the Deeming Rule as having been issued in violation of the Appointments Clause. Defendants Food & Drug Administration, *et al*. (FDA), raise several defenses to Plaintiffs' claim, but none passes scrutiny. FDA's principal defense on the merits—the Associate Commissioner for Policy (ACP) is an inferior officer—fails because Congress has not by law vested the appointment of the ACP in the Secretary for Health and Human Services, and because the Secretary does not appoint the ACP within the meaning of the Appointments Clause. Moreover, even if Congress had vested by law the ACP-appointing power in the Secretary, and the Secretary had properly exercised that power with respect to the ACP, the Deeming Rule would still be infirm because the powers of the ACP may be exercised only by a principal officer. Even were the Secretary to someday withdraw the delegations of power to the ACP or eliminate the office, which would give the career incumbent a civil service claim, such actions would not make any less binding the ACP's already issued regulations (such as the Deeming Rule) which are alterable only by new rulemaking. Furthermore, the independence that this substantial rulemaking authority denotes is amplified by the employment protections afforded the ACP through that position's inclusion in the career Senior Executive Service. These aspects of the ACP render any purported direction and supervision by other persons constitutionally inadequate.

Perhaps sensing the weakness of its defense on the merits, FDA seeks to deprive the Court of the opportunity to reach the constitutional question, citing two supposed ratifications of the Deeming Rule. The agency's reliance on these purported constitutional curatives is misplaced. To begin with, the 2016 Califf ratification is best read as not addressing the Appointments Clause at all, but instead as merely seeking to remedy any irregularities in prior delegations of administrative

authority. Even if the Califf ratification could plausibly be interpreted as an attempt to remedy Appointments Clause violations, it could not do so, given its perfunctory analysis and its failure to address the Deeming Rule specifically. FDA's reliance on the second purported ratification by former Commissioner Gottlieb is also unavailing. A ratification is effective only if the ratifier had the power to ratify at the time of ratification. In April 2019, Commissioner Gottlieb had the power to ratify the Deeming Rule, but only if in compliance with the Administrative Procedure Act. His ratification, however, does not satisfy that key condition because it arbitrarily ignores substantial new evidence undercutting the Deeming Rule's approach to regulating vaping products.

Even if the Gottlieb or Califf ratifications were effective, this Court would not be precluded from reaching the merits of the Appointments Clause claim. Such ratifications are best understood as a strategic voluntary cessation of action otherwise in violation of the Appointments Clause. Without relief from this Court, Plaintiffs will again be subject to FDA's unconstitutional rulemaking practice, given the agency's ongoing efforts to reshape the Deeming Rule's implementation, coupled with its persistent failure to revoke the delegation of power from a still-active, rule-issuing ACP. Moreover, given the substantial evidence produced since the rule's issuance questioning the advisability of the Deeming Rule's regulatory approach, combined with FDA's impliedly acknowledging the same through its extensions of the rule's compliance deadlines, a remand to allow the agency to abide by the Appointments Clause likely would result in a substantially different—and improved—regulatory state of affairs for Plaintiffs and other participants in the vaping industry.

In a final strained attempt to keep the Court from addressing the agency's constitutionally doubtful rulemaking practices, FDA contends that Plaintiffs forfeited their right to vindicate the Constitution's structural safeguards against unaccountable and abusive Executive Branch conduct

by failing to raise their Appointments Clause claim during the rulemaking process. But this Court and other courts have already made clear that such significant constitutional challenges to rulemaking need not be aired during a public-comment process. In any event, the rule of issue exhaustion is not unbending even where it applies, and the equities here weigh heavily in Plaintiffs' favor. In the 18 months since this litigation was commenced, FDA has shown no interest in reforming its constitutionally deficient rulemaking practices, yet the fruit of those practices threatens Plaintiffs' businesses and livelihoods. The Court should reach the merits and hold the Deeming Rule unconstitutional.

I. The Deeming Rule Is Unconstitutional Because It Was Promulgated by an Associate Commissioner for Policy (ACP) Who Served in Violation of the Appointments Clause

A. Ms. Kux was not validly appointed as an inferior officer

FDA's main defense to Plaintiffs' Appointments Clause challenge is that the ACP is an inferior officer validly appointed by the Secretary. Even assuming that an inferior officer may constitutionally execute the duties of the ACP, *but see infra* Part I.B.; Pls. Br. 17–23, FDA's defense still fails. Congress has not by law vested the Secretary with the power to appoint the ACP. And even if it had, the ACP appointing procedure does not satisfy the Appointments Clause.

1. Congress has not by law vested the ACP's appointment with the Secretary

The Appointments Clause requires that Congress must by law vest the power to appoint an inferior officer in the President, a department head, or a court of law. Failing that, even inferior officers must be Senate-confirmed and appointed by the President. Plaintiffs contend that Ms. Kux could not have been validly appointed as an inferior officer because Congress has not vested her appointment with the Secretary. Contrary to FDA's characterization, FDA Br. 37, Plaintiffs' position is not that Congress must specifically provide for the appointment of a particular inferior

officer. Rather, consistent with the Appointments Clause's default preference for Senatorial advice and consent for all officers, *Edmond v. United States*, 520 U.S. 651, 660 (1997), a statute grants inferior-officer appointing authority only when it (i) explicitly authorizes a power to "appoint" and (ii) gives that power to a specific head of department. None of the laws cited by FDA qualifies as such a statute.

In *Edmond*, the Supreme Court laid out the method for interpreting whether a statute vests the power to appoint an inferior officer in a department head. The Court compared two statutes. The first, 49 U.S.C. § 323(a), provides that "[t]he Secretary of Transportation may *appoint* and fix the pay of officers and employees of the Department of Transportation and may prescribe their duties and powers." *Edmond*, 520 U.S. at 656 (emphasis added). The second, Article 66(a) of the Uniform Code of Military Justice, 10 U.S.C. § 866(a), provides that "[e]ach Judge Advocate General shall establish a Court of Criminal Appeals" and that "[a]ppellate military judges who are *assigned* to a Court of Criminal Appeals may be commissioned officers or civilians." *Edmond*, 520 U.S. at 656–57 (emphasis added). *Edmond* held that the former statute, but not the latter, vests the power to appoint inferior officers. Crucial to the Court's holding was the difference in vocabulary between "appoint" and "assign." *Edmond*, 520 U.S. at 657 ("The difference between the power to 'assign' officers to a particular task and the power to 'appoint' those officers is not merely stylistic."). *See United States v. Janssen*, 73 M.J. 221, 224 (C.A.A.F. 2014) ("[W]e interpret *Edmond* to require statutory language specifically granting the head of a department the power to appoint inferior officers."). As *Edmond* demonstrates, Congress knows how to vest the appointment of inferior officers, and it does so by explicitly using the word "appoint."[1]

[1] The Supreme Court's holding in *United States v. Nixon* that the attorney general is authorized by law to appoint a special counsel (who is an inferior officer) is consistent with this approach. *See United States v. Nixon*, 418 U.S. 683, 694 (1974). One of the statutes cited by the Supreme Court

Although Congress has vested the Secretary of Health and Human Services with authority to appoint several types of inferior officers, the ACP is not among them. No statute grants the broad, department-wide appointment power to that Secretary which 49 U.S.C. § 323(a)—at issue in *Edmond*—grants to the Secretary of Transportation. Instead, Congress has chosen to grant narrower appointment powers to the Secretary of Health and Human Services. For example, 42 U.S.C. § 913, which is found in that portion 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*." *Id*. (emphasis added).

In contrast, none of the statutes cited by FDA, FDA Br. 36, grants a general appointment authority to the Secretary. To begin with, 21 U.S.C. § 393(d)(2) gives the Secretary the power to "coordinat[e] and oversee[] the operation of all administrative entities within the Administration," but the power to coordinate and oversee subordinates—which even federal employees may wield—is not the same as the power to appoint officers of the United States. And although 5 U.S.C. § 3131(14) states that "[t]he Senior Executive Service shall be administered so as to . . . appoint career executives to fill Senior Executive Service positions to the extent practicable, consistent with the effective and efficient implementation of agency policies and responsibilities," nowhere does that statute vest any appointment power in the head of any department. Instead, it creates a preference for how already existing appointing power should be used with respect to career Senior Executive Service employees. For its part, 5 U.S.C § 3133 does not identify any specific

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in support of this appointment power is 28 U.S.C. § 533, which states in part: "The Attorney General may appoint officials . . . to detect and prosecute crimes against the United States . . . ." By identifying a particular head of a department and explicitly vesting a power to "appoint," this statute comports with the *Edmond* test.

department head and uses the word "appointment" only in its title, not in any operative provision. Even less persuasive is FDA's citation to 42 U.S.C. § 3501(6), which "authoriz[es] the performance of any of the functions of the Secretary by any other officer, or by any agency or employee, of the Department"—in other words, the provision authorizes the delegation of powers not the appointment of officers. Along the same lines, 5 U.S.C. § 302(b) merely declares that "the head of an agency may delegate to subordinate officials the authority vested in him"; it does not vest an appointment power and names no specific head of department.

Ultimately, FDA's argument founders on the canon against surplusage. *Cf. TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is our duty to give effect, if possible, to every clause and word of a statute.") (internal quotation marks and citations omitted). For if, as FDA contends, the above-cited broadly applicable statutes grant to the Secretary of Health and Human Services a blanket appointment power across all agencies of his Department, then the specific appointment power authorized by 42 U.S.C. § 913 would be unnecessary. Also rendered duplicative would be the many specific authorizations for Secretarial appointment of FDA officials (none of which is for the ACP).[2]

Offering no better support for FDA's position are the agency's case authorities, which construe the Department of Labor's structural statutes to allow for an inferior officer appointment power. FDA Br. 37 (citing *Willy v. Admin. Review Bd.*, 423 F.3d 483, 491–92 (5th Cir. 2005); *Varnadore v. Sec'y of Labor*, 141 F.3d 625, 631 (6th Cir. 1998)). These decisions are inapposite because the Department of Labor's organizing statutes are meaningfully distinguishable from

[2] Congress has granted the Secretary appointment power for various officials enumerated in twenty separate statutes within Title 21 (Food and Drugs), each of which explicitly uses the word "appoint." *See* 21 U.S.C. §§ 355, 355-1, 360c, 360d, 360e, 360kk, 360j, 379d-3, 379d-3a, 379e, 387q, 393, 399a, 454, 603, 604, 606, 616, 621, 661.

those governing the Department of Health and Human Services. "The Labor Department statutes . . . are short, vague, and very old." *Janssen*, 73 M.J. at 224. In contrast, other departments' fundamental statutes—such as those of the Department of Health and Human Services or, at issue in *Janssen*, those of the Department of Defense—go into "great specificity on the powers of the Secretary . . . and the structure of the department." *Id*. In such contexts, it makes little sense to read into a department's general statutes a broad appointment power, as that approach would render superfluous Congress's "enshrining [of specific] positions in statute and providing for their appointment." *Id*. at 225.

Janssen's reasoning applies with equal force here. FDA's interpretation of a few general statutes to confer a blanket appointment power on the Secretary would render over a dozen appointments statutes surplusage. Indeed, FDA's interpretation of 5 U.S.C. §§ 3131 and 3133 would mean that *every* department head is essentially granted the power to appoint any inferior officer he or she wishes, so long as the appointee is a member of the Senior Executive Service. But as another judge of this Court recently explained, "th[e] power to 'keep house,' . . . is not the same as the power to 'build the house' by appointing officers." *United States v. Concord Mgmt. & Consulting LLC*, 317 F. Supp. 3d 598, 622 (D.D.C. 2018). FDA's interpretation "would threaten to swallow up the statutory appointment schemes enacted for various agencies," *id.*, not just for the Department of Health and Human Services. FDA's interpretation should be rejected.

2. The Secretary has not constitutionally exercised any otherwise lawfully delegated power to appoint the ACP

Even if the Secretary had a general power to appoint inferior officers, such power could not have been lawfully exercised with respect to the ACP. As FDA itself acknowledges, under the procedures in place when Ms. Kux was hired (and presumably still in effect), the Secretary was limited to a yes-or-no concurrence, and the authority to select appointees and present them to the

Secretary for concurrence belonged to the FDA Commissioner. FDA Br. 36 n.14 (noting only that "if the Commissioner fails to select a satisfactory candidate, the Secretary can rescind the Commissioner's delegated appointment authority."). Contrary to FDA's suggestion, the fact that the Secretary could rescind the Commissioner's appointment authority, or change the procedure used to appoint the ACP, is irrelevant to whether the procedure actually used to hire Ms. Kux constituted an appointment by a head of department, as the Appointments Clause requires. It did not.

Allowing the choice of ACP to be made by the Commissioner, rather than the Secretary, violates the core purpose of the Appointments Clause, which is to prevent the diffusion of the appointment power. After all, "[t]he Constitutional Convention rejected Madison's complaint that the Appointments Clause did 'not go far enough if it be necessary at all': Madison argued that 'Superior Officers below Heads of Departments ought in some cases to have the appointment of the lesser offices.'" *Freytag v. C.I.R.*, 501 U.S. 868, 884 (1991) (quoting 2 Records of the Federal Convention of 1787, pp. 627–28 (M. Farrand rev. 1966)). Thus, "[t]he Framers understood . . . that by limiting the appointment power, they could ensure that those who wielded it were accountable to political force and the will of the people." *Freytag*, 501 U.S. at 884. For that reason, "[t]he Appointments Clause prevents Congress from distributing power too widely by limiting the actors in whom Congress may vest the power to appoint," and thus "reflects our Framers' conclusion that widely distributed appointment power subverts democratic government." *Id.* at 885. *See Ryder v. United States*, 515 U.S. 177, 182 (1995) ("[The Appointments Clause] 'preserves another aspect of the Constitution's structural integrity by preventing the diffusion of the appointment power.'") (quoting *Freytag*, 501 U.S. at 878). An appointment made by the Commissioner with only a "concurrence" by the Secretary represents just such a "diffusion" of power by allowing the

Secretary to avoid political accountability for the selection of an ACP.

FDA cites *United States v. Hartwell*, 73 U.S. (6 Wall.) 385 (1867), for the opposite conclusion, but that case does not compel acceptance of FDA's hiring procedure as compatible with the Appointments Clause. *Hartwell* turned on the interpretation of the word "officer" as used in a *statute*, so any comments from that case concerning the meaning of "officer" for purposes of the Appointments Clause were unnecessary to the Court's holding. *In re Financial Oversight and Management Board for Puerto Rico*, 318 F. Supp. 3d 537, 552 (D.P.R. 2018), *aff'd in part, rev'd in part*, *sub nom. Aurelius Investment, LLC v. Puerto Rico*, 915 F.3d 838 (1st Cir. 2019), *cert. granted*, 2019 WL 2410935 (June 20, 2019) ("[T]he Court's focus was on the language of the statute and on the general nature of government office, rather than on the Constitutional status of the office held by the defendant."). To be sure, even dicta from the Supreme Court merit significant respect. But here it is appropriate to afford the dicta of *Hartwell* little weight because they are readily distinguishable. *Hartwell* construed the General Appropriation Act of 1866, 14 Stat. 191, 202 (July 23, 1866), which authorized an assistant treasurer to appoint "a specified number of clerks" with the "approbation" of the Secretary of the Treasury. *Hartwell*, 73 U.S. at 393. In contrast, no statute authorizes the ACP's appointment, much less through the perfunctory process of "approbation."[3] *See* 2 FDA Staff Manual Guides § 1431.23(1)(A)-(B) (APP 59) (FDA Commissioner and Deputy Commissioner have authority to establish all Senior Executive Service positions and to make career appointments subject to Secretarial concurrence). Thus, *Hartwell* did

[3] As far as Plaintiffs are aware, the Supreme Court has never sanctioned the appointment-by-approbation of inferior officers outside of specific statutory authorization. *See Free Enterp. Fund v. Public Co. Accounting Oversight Bd.*, 561 U.S. 477, 512 n.13 (2010) (approval-appointment authorized by Reorg. Plan No. 10, § 1(b)(2), 64 Stat. 1265, 1266 (1950)). *Cf. United States v. Smith*, 124 U.S. 525, 532–33 (1888) (holding that a customs clerk was not an inferior officer, even though his appointment was approved by the Secretary of the Treasury, because in part "no law required this approbation").

not countenance the undermining of democratic accountability that FDA's process for ACP selection threatens. Neither should this Court.

B. The ACP's power and lack of supervision require the appointment of a principal officer, yet Ms. Kux was not validly appointed as a principal officer

Plaintiffs contend that, given its substantial powers which may be exercised largely independent of official oversight, the office of ACP can be held only by a principal officer. As FDA correctly summarizes, 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) (quoting *Edmond*, 520 U.S. at 663). FDA puts forward several arguments as to why the ACP's direction and supervision is substantial enough that the ACP's duties may be exercised by an inferior officer. None succeeds.

First, FDA points out that, while the ACP has been delegated rulemaking authority, "the FDA Commissioner . . . retains the power to 'continue to exercise [that] delegated authority.'" FDA Br. 30 (citing 2 FDA Staff Manual Guides § 1410.21(1)(A), (1)(G)(1) (APP 40, 43); 21 C.F.R. § 10.25(b); *id.* § 10.33(a)). This is true but irrelevant to whether the FDA Commissioner supervises the ACP in *the ACP's* exercise of rulemaking authority. The ACP, the Commissioner, and the Secretary each may issue FDA rules. In this respect, they are on an equal footing. Thus, it makes no more sense to say that the Commissioner supervises the ACP's rulemaking power than it does to say that the Commissioner supervises the Secretary's rulemaking power. Indeed, FDA's argument proves too much. If the mere existence of another officer with concurrent authority were enough to make an officer sufficiently supervised, then nearly *every* officer with rulemaking power in the federal government would be sufficiently supervised in his or her exercise of rulemaking power so as to be an inferior officer, because very few rulemaking authorities reside solely in a

single officer. That cannot be right.

Slightly more on point, FDA later observes that "any rule issued by the Associate Commissioner for Policy can be reviewed by the FDA Commissioner under the Commissioner's retained rulemaking authority." FDA Br. 31 (citing 2 FDA Staff Manual Guides § 1410.21(1)(A) (APP 40); 21 C.F.R. § 10.25(b); *id.* § 10.33(a)). But the review procedures that FDA highlights do not establish adequate supervision, because they either merely affirm concurrent authority or allow for a reconsideration action only *after* the ACP has taken final agency action. *See* 2 FDA Staff Manual Guides § 1410.21(1)(A) ("The Commissioner may continue to exercise all delegated authority . . . ."). *See also* 21 C.F.R. § 10.40(h) ("The record of the administrative proceeding closes on the date of publication of the final regulation in the Federal Register unless some other date is specified. *Thereafter*, any interested person may submit a petition for reconsideration under § 10.33 or a petition for stay of action under § 10.35.") (emphasis added). For example, although the Commissioner may on his own initiative reconsider a matter, *id*. § 10.33(a), he may do so only "after it has been decided or action has been taken," *id.* § 10.33(h). And such a point is reached, with respect to rules that ultimately are issued, only by "promulgat[ion of] a final regulation." *Id*. § 10.40(c). Once, however, a rule has been published, it is a final and binding agency action. *See id.* § 10.45(d) ("Unless otherwise provided, the Commissioner's final decision constitutes final agency action . . . on the issuance of a final regulation published in accordance with § 10.40 . . . ."). To reconsider or amend such a decision would require FDA to go through the full Administrative Procedure Act process for rulemaking, because a notice-and-comment rule can be amended or rescinded only by a notice-and-comment rulemaking. *City of Idaho Falls v. F.E.R.C.*, 629 F.3d 222, 227 (D.C. Cir. 2011). *Accord* 21 C.F.R. § 10.25(b) (the Commissioner must initiate "a proceeding" in order to "amend . . . or revoke a regulation"). Thus, none of the purported "review"

provisions that FDA points to meets the *Edmond* standard for sufficient supervision, because they still allow the ACP to "render a final decision on behalf of the United States" without prior permission of the Secretary or the Commissioner. *See Edmond*, 520 U.S. at 665.

FDA fares no better in relying on its staff manual's reservation to the Secretary of "the authority to approve any FDA regulations presenting 'highly significant public issues.'" FDA Br. 30 (quoting 2 FDA Staff Manual Guides § 1410.10(2)(A)(2) (APP 27, 38)). To begin with, the manual does not define "highly significant public issues," nor does it suggest how many FDA rules fall into this category. More importantly, by implied necessity the manual reserves to the ACP the authority to issue—evidently without any oversight—all rules not touching upon "highly significant public issues,"[4] which rules are final decisions on behalf of the United States, *see* 21 C.F.R. § 10.45(d). Thus, the Secretarial oversight preserved by the manual still falls short of the *Edmond* standard. *See Edmond*, 520 U.S. at 665 (noting that the officers in question "ha[d] *no power* to render a final decision on behalf of the United States unless permitted to do so by other Executive officers") (emphasis added).

Similarly unavailing is FDA's reliance on the administrative-state-wide requirement that "significant regulatory actions" must be reviewed by the Office of Information and Regulatory Affairs (OIRA). FDA Br. 30 (citing Exec. Order (E.O.) No. 12,866 § 6(b), 58 Fed. Reg. 51,735 (Sept. 30, 1993); AR 28,886–29,460). This argument fails for the same reason that FDA's argument premised on its staff manual's reservation of rulemaking for "highly significant public

[4] Given the notable silence on the point in FDA's brief, that category of rules exempted from Secretarial oversight includes the Deeming Rule. And if the Deeming Rule—which threatens to eliminate an entire industry—is not considered to raise a "highly significant public issue," then the oversight that the staff manual guarantees is quite limited indeed. Confirming this, the ACP has historically issued 98% of FDA rules. *See* Angela C. Erickson & Thomas Berry, *But Who Rules the Rulemakers? A Study of Illegally Issued Regulations at HHS* 25 and note 18 (Table 1) (Apr. 29, 2019).

issues" fails—significant rules are only a subset of the rules that the ACP may issue, and thus the ACP possesses authority to render a final decision on behalf of the United States without permission of OIRA for all rules other than those deemed "significant regulatory actions." Moreover, the argument falters for another reason: even where applicable, OIRA review is not plenary; it is limited to particular tasks, such as cost-benefit analysis and paperwork reduction. *See* E.O. 12,866, § 6(b); 44 U.S.C. §§ 3501–3521. FDA offers no support for its claim that OIRA directs and supervises (for Appointments Clause purposes) the exercise of all significant rulemaking discretion throughout all executive departments and, thus, is the only department in which a principal officer need actually be appointed. In fact, that OIRA review does not extend to the policy choices underlying agency rulemaking—such as whether deeming as "tobacco products" items that contain no tobacco—underscores the independence, and thus the principal-officer status, of the ACP.[5] *Cf. Intercollegiate*, 684 F.3d at 1339 (a supervisory power extending to questions of law but not questions of fact "fall[s] short of the kind that would render [otherwise principal officers] inferior officers").

Perhaps recognizing the inadequacy of the foregoing methods for preserving real direction and supervision over the ACP's work, FDA emphasizes the provisions of its staff manual that allow for the rescission of the ACP's rulemaking authority. FDA Br. 30 (citing 2 FDA Staff Manual Guides § 1410.10(1)(A)(14) (APP 19–20); 2 FDA Staff Manual Guides § 1410.21(1)(A) (APP 40)). Presumably FDA means to argue that such power amounts to a *de facto* removal prerogative. If so, then the argument fails for two reasons. First, the ACP possesses far more

[5] Further, FDA's argument once again proves too much. Most federal rulemakers must submit significant rules for OIRA review. *See* E.O. 12,866, § 6. Hence, if such "oversight" were enough to make the ACP an inferior officer, then even many heads of department would be considered inferior officers. That outcome is implausible.

significant authority than just her rulemaking power. *See* 2 FDA Staff Manual Guides § 1410.21(1)(G) (Sept. 21, 2016) (APP 52–53) (vesting a comprehensive set of powers in the ACP including, among others, authority to "issue responses to . . . [p]etitions for reconsideration," "[p]etitions for stay," and "[r]equests for advisory opinions" made pursuant to 21 C.F.R. §§ 10.33, 10.35, 10.85). The Supreme Court, however, has never suggested that the loss of a single power is enough for a supervisor to exercise sufficient control; it is rather "[t]he power to remove officers" that is "a powerful tool for control." *Edmond*, 520 U.S. at 664. Thus, the *de facto* removal of the ACP should entail the withdrawal of all significant powers, not just rulemaking. Second, even if the FDA's internal staff manuals do not constrain the Secretary's or the Commissioner's power to rescind all of these ACP powers, the civil service statutes do. "[B]y virtually any definition, essentially all [Senior Executive Service] officials . . . 'direc[t] the work of an organizational unit,' carry out high-level managerial functions, or '*otherwise exercis[e] important policy-making, policy-determining, or other executive functions*.'" *Free Enterprise Fund*, 561 U.S. at 542 (Breyer, J., dissenting) (quoting 5 U.S.C § 3132(a)(2)). To deprive such an official of the policy-making or other high-level executive functions that make the office worthy of the Senior Executive Service therefore requires observance of the statutory procedure for removal from that Service. *See, e.g.*, 5 U.S.C. § 7543(a) (limiting most suspensions or removals to "misconduct, neglect of duty, malfeasance, or failure to accept a directed reassignment or to accompany a position in a transfer of function").

FDA argues to the contrary, contending that the ACP's removal protections "still allow substantial control."[6] FDA Br. 32. The agency elaborates that "[t]he SES statute lists particular

[6] FDA's reliance on *Free Enterprise Fund*, FDA Br. 32, which dealt with members of the Public Company Accounting Oversight Board, is misplaced, as the Court "d[id] not decide the status of other Government employees." *Free Enterprise Fund*, 561 U.S. at 506.

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." *Id.* (citing 5 U.S.C. § 2302(b)) (emphasis added). The agency's characterization of the statute is not a fair one. To be sure, section 2302 of Title 5 lists prohibited grounds for "personnel actions," but these do *not* include removals.[7] *See* 5 U.S.C. § 2302(a)(2)(A) (addressing inter alia "an appointment; a promotion; . . . [or] a detail, transfer, or reassignment").

Neither the Supreme Court nor the D.C. Circuit has ever suggested that mere reassignment is analogous to removal as a "powerful means of control." Rather, a long line of authority affirms that it is removal—and only removal—that is the relevant criterion. *See, e.g.*, *Edmond*, 520 U.S. at 664; *Bowsher v. Synar*, 478 U.S. 714, 726 (1986) ("Once an officer is appointed, it is only the authority that can remove him, and not the authority that appointed him, that he must fear and, in the performance of his functions, obey.") (internal quotation marks and citation omitted); *Myers v. United States*, 272 U.S. 52, 117 (1926) (noting that the president's "power of removing those for whom he cannot continue to be responsible" is "essential to the execution of the laws by him"); *The Constitutional Separation of Powers Between the President and Congress*, 20 Op. O.L.C. 124, 150 (1996) ("[T]he most important issues are the extent of the officer's discretion to make autonomous policy choices and the location of the powers to supervise and to remove the officer.").

Strangely, FDA's brief ignores the federal statutes governing removal of Senior Executive Service personnel, 5 U.S.C. §§ 7541–7543. Under these laws, the ACP possesses *for-cause* removal protection, which is precisely the level of removal protection that has been held to be insufficient to satisfy the *Edmond* supervision factor. *See Intercollegiate*, 684 F.3d at 1339–40

[7] In fact, the cited statutory provision bestows no authority of any kind; it merely limits otherwise granted authority. *See* 5 U.S.C. § 2302(b) ("Any employee *who has authority* to take, direct others to take, recommend, or approve any personnel action, shall not . . . .") (emphasis added).

(explaining that "[t]he second *Edmond* factor, removability, also supports a finding that the [copyright royalty judges] are principal officers" because, "[u]nlike the judges in *Edmond,* the [copyright royalty judges] can be removed by the Librarian [of Congress] only for misconduct or neglect of duty").

Not only does the ACP possess for-cause removal protection from her overall employment, she also possesses for-cause protection from demotion outside the Senior Executive Service. Once such a career civil servant has served for at least one year (as Ms. Kux had when she proposed and then promulgated the Deeming Rule), that person can be removed from the Senior Executive Service and transferred to a civil service position outside that rank only for the reason of "less than fully successful executive performance."[8] 5 U.S.C. § 3592(a)(2). Just two exceptions to this for-cause removal protection exist but, contrary to FDA's contention, neither plausibly can be construed to allow for removal for policy differences. *See id.* § 7532 (authorizing suspension or removal from the Senior Executive Service when the head of an agency considers it necessary for the interests of national security); *id*. § 3595 (authorizing removal from the Senior Executive Service in the special circumstance of an overall reduction in force).

FDA's authority purporting to downplay the significance of such removal protections is unpersuasive. The agency cites *Morrison v. Olson*, 487 U.S. 654 (1988), for the proposition that for-cause removal protection is consistent with inferior-officer status. *See* FDA Br. 33. But *Morrison* "clearly did not hold that such a restriction on removal was generally consistent with the status of inferior officer." *Intercollegiate*, 684 F.3d at 1340. Instead, *Morrison* turned on "the

[8] Although unsatisfactory performance can lead to removal from the Senior Executive Service, FDA Br. 32 n.10, the criteria for grading performance are efficiency, productivity, timeliness, quality of work, and similar considerations, *not* the degree to which one accepts superiors' policy preferences. *See* 5 U.S.C. § 4313(1)–(6).

Court's view that the independent counsel also 'performed only limited duties, that her jurisdiction was narrow, and that her tenure was limited [to performance of a "single task"].'" *Intercollegiate*, 684 F.3d at 1340 (quoting *Edmond,* 520 U.S. at 661). The ACP, in contrast, enjoys rulemaking authority across much of FDA's jurisdiction, a significant power which the ACP holds for unlimited duration. Similarly unhelpful is FDA's citation to *United States v. Perkins*, 116 U.S. 483 (1886). FDA Br. 32. Although not explicitly overruled, the reasoning of *Perkins* has not survived *Edmond*. *See Concord Mgmt.*, 317 F. Supp. 3d at 614 ("It is unlikely that the broad and dated language of *Perkins* survived *Edmond*, which demands that inferior officers be subordinate to superiors and does not contemplate allowing unremovable officers if 'for the public interest.'").

To be sure, FDA is correct that the ultimate weight of the *Edmond* factors depends in part on whether the terms of an officer's oversight, decision-making, and removal are subject to alteration by the officer's superiors. *In re Grand Jury Invest.*, 916 F.3d 1047, 1052–53 (D.C. Cir 2019). And no doubt some of the ACP's inadequate supervision could be remedied by Secretarial or Commissioner action. But what is striking is just how much cannot be remedied or undone. Unlike, for example, the special counsel at issue in *In re Grand Jury Investigation*, the ACP may—without supervisorial approval—issue binding legislative rules, like the Deeming Rule, which cannot be changed by anyone (including the President) without a subsequent rulemaking. *Compare* 28 C.F.R. § 600.6. And again unlike a special counsel, the ACP *by statute* cannot be stripped of her significant authority or removed from office at will. *Compare In re Grand Jury Invest.*, 916 F.3d at 1052 (a special counsel "effectively serves at the pleasure of [a principal] officer"). Thus, even with a discount for the delegation-revocation power retained by the Secretary and Commissioner, the *Edmond* factor analysis still decisively supports the ACP's principal-officer status. And because it is undisputed that Ms. Kux was not properly appointed as a principal officer,

she had no constitutional authority to issue the Deeming Rule.

II. The Court Should Address the Merits of Plaintiffs' Appointments Clause Challenge, Notwithstanding the Purported Ratifications of the Deeming Rule

FDA argues that the Court should not reach the merits of Plaintiffs' Appointments Clause claim because, regardless of whether Ms. Kux's issuance of the Deeming Rule violated that Clause, two Commissioners have ratified it. FDA's ratification argument must be rejected for three independent reasons. First, the purported ratifications were either too perfunctory to pass scrutiny or failed to address developments since the rule was issued, thereby rendering them arbitrary and capricious in violation of the Administrative Procedure Act. Second, because the purported ratifications (even if effective) do not alter the delegation of rulemaking power to the ACP, the voluntary cessation exception to mootness applies. And finally, even if the ratifications are effective and not subject to a mootness exception, FDA's efforts to alter the Deeming Rule's deadlines confirm that a remand for compliance with the Appointments Clause would likely result in a substantial change to the rule.

A. The purported ratifications were ineffective because they were perfunctory or failed to account for developments since the Deeming Rule was improperly issued

A ratification is effective only if the ratifier had authority to ratify at the time of ratification. *FEC v. NRA Political Victory Fund*, 513 U.S. 88, 98 (1994). Neither purported FDA ratification here is effective because neither comports with the requirements for effective ratification and lawful agency rulemaking. FDA cites then-Commissioner Califf's supposed ratification but does not even attempt to show that it was enough under this Court's and the D.C. Circuit's case law. Nor could the agency make such a showing. The Califf ratification purports to "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" September 2016. *See* APP 144. This ratification is best read

to approve prior actions taken without proper statutory or administrative delegation, rather than actions taken in violation of the Appointments Clause. What's more, it identifies neither whose actions nor which actions are being ratified. It is frankly improbable that Commissioner Califf was aware of all the actions he was purporting to ratify, much less that his ratification reflected careful deliberation about every one of those actions. *Cf. Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 796 F.3d 111, 117 (D.C. Cir. 2015) (for a ratification to be effective, "a properly appointed official" must have "the power to conduct an independent evaluation of the merits" *and* have actually "do[ne] so"). Tellingly, in arguing that the standard for ratification has been satisfied, FDA discusses only the Gottlieb ratification. *See* FDA Br. 22. A superficial ratification on the order of Commissioner Califf's fails to accept accountability for the actions being ratified. If such could satisfy the Appointments Clause, that constitutional safeguard would cease to serve its function, as no officer would ever have to take responsibility for any rule.

Although the Gottlieb ratification at least identifies the Deeming Rule and articulates a barebones recitation of factors considered in ratifying the rule, it too is deficient because it fails to account for the substantial developments that preceded the ratification. As noted, under *NRA Political Victory Fund*, a ratification is valid only if, at the time of the ratification, the ratifying official had the authority to take the action. In *NRA Political Victory Fund*, the Solicitor General's attempt to ratify an earlier filed petition for certiorari was ineffective because the filing deadline had passed, meaning that he could not file the petition in the first instance at that time. *NRA Political Victory Fund*, 513 U.S. at 98–99. The same is true here. Commissioner Gottlieb could not, in April 2019, issue the Deeming Rule without addressing the substantial developments that have occurred since its issuance, as doing so would be arbitrary and capricious under the

Administrative Procedure Act. *See Butte County v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010).[9]

FDA offers four unconvincing responses to this argument. First, the agency argues that new studies clarifying the scientific uncertainties acknowledged in the Deeming Rule are irrelevant because they were not presented to Commissioner Gottlieb prior to his purported ratification. *See* FDA Br. 24 n.4. But any suggestion that Commissioner Gottlieb could not have been aware of the studies is implausible. In fact, FDA and former-Commissioner Gottlieb commented on several of those studies. *See* National Academies of Sciences, Engineering, and Medicine, *Public Health Consequences of E-Cigarettes* 141, 493, 546–49, 558–60, 562–67, 575–79, 582–83, 602–03, 632, 635 (2018)[10] (discussing studies cited by Plaintiffs' motion at footnotes 17–20, 22–23); Press Release, FDA, *FDA In Brief: National Academies of Sciences, Engineering, and Medicine releases FDA-commissioned report on the potential public health consequences of e-cigarettes* (Jan. 23, 2018)[11] (Commissioner Gottlieb's commenting on the report, including its finding that switching to e-cigarettes may improve smokers' health). At least one of the studies was funded, designed, and conducted in part by FDA. *See* Maciej L. Goniewicz, *et al*., JAMA Network, *Comparison of Nicotine and Toxicant Exposure in Users of Electronic Cigarettes and Combustible Cigarettes* 13 (Dec. 14, 2018).[12] Commissioner Gottlieb himself has acknowledged that these studies clarify the

[9] FDA criticizes Plaintiffs' reliance on *Butte County* because the decision does not address an Appointments Clause claim but rather the Administrative Procedure Act's limits on agency rulemaking. FDA Br. 24 n.4. The distinction has no relation to the relevant issue. The Supreme Court's deadline for filing petitions for certiorari "is not an Appointments Clause issue" either, *see id*. at 24, yet the Supreme Court rejected a purported ratification because it fell outside this deadline. *See FEC v. NRA Political Victory Fund*, 513 U.S. 88 (1994). The relevant issue is whether the ratification would be consistent with some other limit on the agency's or the official's authority, not whether that limit relates to the Appointments Clause.

[10] *Available at* https://bit.ly/2Gd216b.

[11] *Available at* https://bit.ly/2XybPDt.

[12] *Available at* https://bit.ly/2x9lv8H.

success of vaping products in helping smokers to quit. *See* Brookings Inst., A Conversation with FDA Commissioner Scott Gottlieb on His Tenure and Policy Reforms 10 (Mar. 19, 2019)[13] ("We do see evidence now that adult smokers are transitioning. . . . [Y]ou see adults fully transitioning to these products.").[14] And perhaps most importantly, FDA's argument would put Appointments Clause plaintiffs in a catch-22. Under *State National Bank of Big Spring v. Lew*, they must identify new evidence or arguments that they would present if given the opportunity for notice-and-comment. *See* 197 F. Supp. 3d 177, 185 (D.D.C. 2016). Yet FDA asserts that these arguments must be ignored precisely because they are new. *See* FDA Br. 24.

Second, and relatedly, FDA argues that any consideration of this new evidence would "impermissibly second-guess the agency's expert judgment based on extra-record evidence[.]" FDA Br. 24. But this assertion misperceives a court's role in considering whether to allow a purported ratification to preclude consideration of the merits of an Appointments Clause claim. Plaintiffs do not ask the Court to second-guess FDA's analysis of these studies or the wisdom of the Deeming Rule. In fact, Plaintiffs couldn't ask for such a Monday-morning-quarterback review because there's no analysis to second-guess—the ratification fails to account for these developments. What Plaintiffs actually seek is for FDA to undertake the regulatory quarterbacking in the first instance, by having the Court reach the merits and then order the agency to return to the rulemaking line of scrimmage.

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[13] *Available at* https://brook.gs/2WuyUTG.

[14] The best reading of the ratification is that Commissioner Gottlieb did not consider any of these post-Deeming Rule studies—a reading which FDA implicitly concedes. FDA Br. 24 (criticizing Plaintiffs' reliance on these studies because they weren't presented to Commissioner Gottlieb). The Court should not presume otherwise, *i.e.*, Commissioner Gottlieb considered and rejected these studies *sub silentio*, because this would present its own Administrative Procedure Act problem. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency must publicly "examine the relevant data and articulate a satisfactory explanation for its action").

Third, FDA argues that the new studies are similar to older studies and thus do not show that vaping devices "should be left entirely unregulated[.]" FDA Br. 26. But Plaintiffs do not need to make such a showing, nor does FDA provide any authority to the contrary. The relevant issue is whether the failure to account for these developments renders the ratification—which must be assessed as if the 2016 final rulemaking had never happened—arbitrary and capricious. It does. *See Butte County*, 613 F.3d at 194 ("[A]n agency's refusal to consider evidence bearing on the issue before it constitutes arbitrary agency action within the meaning of [the Administrative Procedure Act]."). As Plaintiffs explained in their opening brief, Pls. Br. 31–35, the new studies shed light on the scientific uncertainties acknowledged in the Deeming Rule. FDA does not deny that fact. Thus, the new studies suggest that a renewed notice-and-comment process would take these developments into account, and any new rule would benefit from this updated analysis.

Fourth, and finally, FDA attacks a straw man. As the agency points out, the D.C. Circuit has held that an Appointments Clause violation does not necessarily require "a repetition of the procedures initially followed." *Lew*, 197 F. Supp. 3d at 184 (citing cases). But Plaintiffs make no such categorical demand. Instead, they argue that a redo is required because the developments since the Deeming Rule was issued in violation of the Appointments Clause make any attempted ratification that fails to address those developments arbitrary and capricious. FDA has identified no case that conflicts with this analysis.

B. Because the ACP retains continuing authority to issue regulations without supervisorial sign-off, the voluntary mootness exception authorizes the Court to address the merits of the Appointments Clause claim

Although the D.C. Circuit has described ratification as a resolution on the merits of an Appointments Clause claim, it has done so only in cases where such a claim was asserted as a defense to an individual enforcement action. *See Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 12–17 (D.C. Cir. 2019). The Court has also acknowledged that pre-

enforcement challenges to agency rules may require a different analysis and—without deciding the issue—has suggested that such challenges could be analyzed under mootness principles. *See id*. (declining to resolve the question because the plaintiff had failed to show that any of the exceptions to mootness would apply to his case).

If the FDA ratifications are valid, mootness is the correct lens to analyze their effect on this case. FDA's arguments to the contrary merely beg the question. *See* FDA Br. 27 (quoting *Guedes* without analysis). The purported ratifications do not cure the underlying violation—someone still issued the Deeming Rule while serving in violation of the Appointments Clause. Nor do they address the source of that violation: the delegation of rulemaking authority to a mere agency employee. Instead, the purported ratifications raise the prospect that these questions are now moot because someone with proper constitutional authority has taken responsibility for the rule.

Here, the voluntary cessation exception to mootness applies. When a defendant voluntarily attempts to cure the particular instance of harm that plaintiffs challenge, courts should proceed to the merits unless the defendant has conclusively established that the challenged activity is not likely to recur. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000). FDA's sole response to voluntary cessation is that Ms. Kux is no longer serving as the ACP. FDA Br. 27–28. But that misses the point. Turnover is common; hence Appointments Clause cases properly focus on the office, not the individual who happened to occupy the office at a particular time. Here, Plaintiffs challenge the issuance of a rule by the then-occupant of the ACP office, a mere employee, under a delegation that purports to give that employee rulemaking authority in violation of the Appointments Clause. Thus, although Ms. Kux is unlikely to issue a future rule, the ACP likely will. FDA's standard operating procedure is to have mere employees issue regulations. *See* Erickson & Berry, *supra*, at 25, note 18 (Table 1), and 35-36 (Appendix C1)

(showing that FDA employees, rather than properly appointed officers, issued 1,860 of 1,891 FDA rules over a 17-year period, or 98% of those rules). Although the Commissioner has issued one recent rule himself, FDA hasn't even suggested that it intends to change its standard rulemaking practice. *See* FDA Br. 27 n.6. And the purported ratifications deny any constitutional impropriety. Ratification of Deeming Rule (Apr. 3, 2019), APP 231. Since this case was filed—and, in fact, even since FDA's cross-motion was filed—Ms. Kux's successor as ACP has continued to issue rules under this delegation. *See* 84 Fed. Reg. 27,200 (June 12, 2019); 84 Fed. Reg. 16,205 (Apr. 18, 2019).

Thus, it is likely that FDA will issue additional rules that harm Plaintiffs and that such rules will be unconstitutionally issued by an employee occupying the position of ACP. *See* Pls. Br. 40. FDA does not contest these likelihoods. FDA Br. 27–28. Nor could it. The Deeming Rule acknowledges that it was enacted in the face of substantial uncertainty and that additional clarification may be required. *See* 81 Fed. Reg. 28,974, 29,010 (May 10, 2016). Former Commissioner Gottlieb has acknowledged the likelihood of additional rules, and FDA has demanded that vaping companies turn over new research which could be used to craft additional rules. *See* Pls. Br. 40.

Therefore, FDA's reliance on *Guedes* is misplaced. In that case, the risk of party manipulation—the chief mischief that the voluntary cessation doctrine seeks to avoid—was absent. The appointment of an Attorney General ended the service of the improperly appointed acting attorney general and the office itself. *See Guedes*, 920 F.3d at 15. Thus, the mootness was the result of the independent action of parties not before the court—the President and the Senate—making the risk of party manipulation extremely remote. *See id*. at 15–16. Here, by contrast, the only actor who has purportedly tried to moot this case—the FDA Commissioner—has been a party

all along. And he has taken no step to prevent the violation from recurring but has instead denied any wrongdoing. Consequently, *Guedes* provides no support for FDA's argument that the voluntary cessation exception is inapplicable.

FDA's only remaining argument on mootness is the bare assertion in a footnote that Plaintiffs' requested injunction against enforcement of the Deeming Rule would provide no redress against future rules. FDA Br. 27–28 n.6. The agency's argument ignores Plaintiffs' request for declaratory relief and "any other relief that the Court determines to be just and proper." Compl. 16–17. Through this case, Plaintiffs seek to bind FDA to the principle that rules issued by a mere employee violate the Appointments Clause, an outcome that would clearly bear on future vaping-related rules issued by FDA employees like the ACP. And contrary to FDA's suggestion, a defendant's voluntary cessation of challenged activity does not deprive a plaintiff of standing to attack that activity. *See Friends of the Earth*, 528 U.S. at 185–88.

C. FDA's efforts to modify the Deeming Rule's compliance deadlines demonstrate that a renewed notice-and-comment process would result in significant changes to the rule

Even if FDA's ratifications are lawful, and even if their impact on this case is not analyzed through the lens of mootness, they still should not prevent the Court from reaching the merits because it is likely that a renewed notice-and-comment process would affect any new rule. FDA disputes the standard that applies to ratification, arguing for a harmless-error rule rather than *Legi-Tech*'s standard that it must be "virtually inconceivable that a new rule would differ from the challenged one." Although the latter standard is the proper one, *see* Pls. Br. 30, the ratifications do not preclude resolution of the merits under either standard. The harmless-error rule merely requires a showing of some prejudice; it "does not 'impose a . . . particularly onerous requirement.'" *See Oglala Sioux Tribe v. U.S. Nuclear Reg. Comm'n*, 896 F.3d 520, 535 (D.C. Cir. 2018) (citation

omitted). *Cf. 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 Administrative Procedure Act's "harmless error" rule).

The question, under either standard, is whether requiring the agency to start the process over would likely affect the outcome (although the likelihood varies under the two competing standards) or whether a redo would be futile, "'do[ing] nothing but giv[ing] [the plaintiffs] the benefit of delay.'" *See Wilkes-Barre Hosp. Co., LLC v. N.L.R.B.*, 857 F.3d 364, 372 (D.C. Cir. 2017) (quoting *Doolin Sec.*, 139 F.3d at 214). FDA counters that the question is whether "but for the improperly appointed decisionmaker's decision, the properly appointed decisionmaker would have reached a different result." FDA Br. 21. It's not clear what this means but, if it is meant to suggest something other than the inquiry above, it is mistaken. In every case considering ratification, the D.C. Circuit has properly asked whether requiring the agency to restart the process tainted by the Appointments Clause violation would be futile or would likely lead to a material change in the outcome. *See, e.g.*, *Doolin*, 139 F.3d at 214 (question is whether "redoing the administrative proceedings would bring about the same outcome"); *FEC v. Legi-Tech, Inc.*, 75 F.3d 704, 708–09 (D.C. Cir. 1996) ("[I]t is virtually inconceivable that its decisions would differ in any way the second time from that which occurred the first time."). *Accord Lew*, 197 F. Supp. 3d at 185 (there would be continuing prejudice, despite a purported ratification, if plaintiffs articulated the substance of any new comments they would make in a new notice-and-comment period or explained how the resulting rule would likely differ from the improperly promulgated one).

Here, that likelihood has been demonstrated through FDA's actions to modify the Deeming Rule. FDA has amended the rule seven times through regulatory guidance documents, including delaying the compliance date. *See* FDA, *Extension of Certain Tobacco Product Compliance*

Deadlines Related to the Final Deeming Rule at 15 (Mar. 2019).[15] FDA observes that one of these guidance documents has been vacated. *See Am. Acad. of Pediatrics v. FDA*, No. PWG-18-883, 2019 WL 2123397, at *26 (D. Md. May 15, 2019). But this strengthens rather than weakens Plaintiffs' argument. The guidance was struck down because it was not properly promulgated through notice-and-comment. *See id.* Thus, the court's decision to vacate the guidance increases the likelihood, were this Court to rule in Plaintiffs' favor, that the changes in the guidance document would be incorporated into a new notice-and-comment Deeming Rule. FDA makes no suggestion to the contrary.

FDA's remaining contention is that its numerous guidance documents changing the Deeming Rule are irrelevant because they do not alter the rule's "substance." *See* FDA Br. 26 & n.5. But the agency provides no reason for why this is so or dispositive. Whether a rule is in effect can be as important, if not more important, as the minute details of the rule. In this case, the difference is between Plaintiffs' ability to manufacture and sell their products or a prohibition on the same. And in any event, *American Academy of Pediatrics*'s requirement that the compliance date extensions must undergo notice and comment proves that they are significant changes to the Deeming Rule. *See Am. Academy of Pediatrics*, 2019 WL 2123397, at *19 (the guidance is reviewable final agency action because it allows products to remain on the market which would otherwise be prohibited, unless first approved through premarket review); *id*. at *26 (notice and comment are required because the guidance "tells manufacturers when they must submit their applications, reports, and requests for new tobacco products").

[15] *Available at* https://bit.ly/2WY66GE.

III. Plaintiffs May Assert Their Appointments Clause Challenge Against the Deeming Rule

FDA contends that Plaintiffs forfeited any argument under the Appointments Clause by failing to raise the issue during the comment period on the proposed Deeming Rule. The agency's contention is without merit: forfeiture does not apply to challenges—like Plaintiffs' Appointments Clause claim—that seek to vindicate "constitutionally mandated structural interests." *Estes v. U.S. Dep't of the Treasury*, 219 F. Supp. 3d 17, 37 (D.D.C. 2016) (citing *Noel Canning v. N.L.R.B.*, 705 F.3d 490, 497 (D.C. Cir. 2013), and *Freytag*, 501 U.S. at 879).

FDA attempts to distinguish this rule, as articulated in *Estes*, principally on the ground that Plaintiffs challenge both the proposed and the final Deeming Rule. According to FDA, unlike the plaintiffs in *Estes* who challenged only a final rule, Plaintiffs here had reason to object to Ms. Kux's participation in the formulation of the Deeming Rule prior to its finalization. The agency's reliance on this distinction is misplaced. To begin with, *Estes* held that the plaintiffs' ignorance of the Appointments Clause violation until after the close of the comment period was merely a sufficient, not necessary, basis for rejecting forfeiture. An equally convincing and independent reason for rejecting forfeiture was the Court's conclusion that an Appointments Clause claim is, by its weighty constitutional nature, generally immune to forfeiture. *See Estes*, 219 F. Supp. 3d at 37 ("For both of the above reasons, the Court will consider the merits of Plaintiffs' Appointments Clause argument."). Moreover, although FDA is correct that Plaintiffs challenge the constitutionality of Ms. Kux's participation in the entire rulemaking process, Plaintiffs could not have known who would issue the final Deeming Rule until after the comment period had closed. Hence, even if FDA's strict understanding of the demands of issue exhaustion were correct—that is, even if Plaintiffs had forfeited their challenge to the proposed rule—

Plaintiffs would still be entitled to a decision on the merits concerning their challenge to Ms. Kux's issuance of the final Deeming Rule.

But the Court need not refine the analysis that far because any application of the forfeiture rule to Plaintiffs would be unjust and therefore unwarranted. Like most parties regulated by the vaping rule, Plaintiffs are small businesses that do not have counsel on retainer to make constitutional arguments far beyond the types of quotidian issues—such as the operational or economic impact to a business—that one might fairly expect unrepresented regulated parties to raise in rulemaking. *Cf. Koretoff v. Vilsack*, 707 F.3d 394, 399–400 (D.C. Cir. 2013) (Williams, J., concurring) ("[P]arties to a litigation obviously have a far clearer burden to speak up to protect their interests than do all of the potentially millions of persons that may be affected by a rulemaking."). The significance of this distinction between rulemaking and adjudication is reflected in the case law. Indeed, other than *Estes*, FDA's cited authority concerns the forfeiture of Appointments Clause claims for failure to raise them in adjudicatory contexts, precisely when one would expect parties to be represented by counsel. *See* FDA Br. 18 (citing *Lucia v. SEC*, 138 S. Ct. 2044, 2055 (2018) (Appointments Clause challenge to an agency adjudication must be "timely") (quoting *Ryder*, 515 U.S. at 182–83), *Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 574 F.3d 748, 755–56 (D.C. Cir. 2009) (failure to raise claim in opening brief on appeal), *In re DBC*, 545 F.3d 1373, 1377–78 (Fed. Cir. 2008) (failure to raise claim before patent appeals board), *Teamsters Local Union No. 455 v. N.L.R.B.*, 765 F.3d 1198, 1201 (10th Cir. 2014) (failure to raise claim before labor board, where parties were "ably represented"), *Kabani & Co., Inc. v. SEC*, 733 F. App'x 918, 919 (9th Cir. 2018) (failure to raise claim in appellate briefing and before accounting oversight board). Accordingly, whatever the strength of FDA's forfeiture argument in adjudications, it has none in the rulemaking context.

That conclusion stands despite FDA's protestations of prejudice. *Cf.* FDA Br. at 20. The agency's conduct after the Deeming Rule's promulgation demonstrates that any Appointments Clause objections would have been futile. After all, this litigation has been active for nearly 18 months. Yet FDA has shown no interest in rectifying the source of the constitutional problem—delegation of substantial and unsupervised rulemaking power to the ACP—and instead has resorted to perfunctory "ratifications" of the Deeming Rule. And even more important than any possible prejudice to FDA is the tremendous harm that forfeiture would inflict upon Plaintiffs—they, not the agency, are the ones who stand to lose their businesses and livelihoods, thanks to an FDA rule that they contend violates the Constitution's essential structural safeguards against unaccountable executive action. Thus, not just on the legal but on the prejudice ledger as well, Plaintiffs' accounts are the stronger. The Court should address the merits of the Appointments Clause claim. *Cf.* Jeffrey S. Lubbers, *Fail to Comment at Your Own Risk: Does Issue Exhaustion Have a Place in Judicial Review of Rules?*, 70 Admin. L. Rev. 109, 155 (2018) ("[I]t would be the rare case where constitutional claims should be disallowed due to issue exhaustion.").

Conclusion

Plaintiffs' motion for partial summary judgment should be granted, and FDA's cross-motion denied.

DATED: July 2, 2019.

Respectfully submitted,

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Case Name: RAVE SALON INC v. GOTTLIEB et al
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Document Number: 42

Docket Text:
Memorandum in opposition to re (28 in 1:18-cv-00203-CRC) Cross MOTION for Partial Summary Judgment filed by MOOSE JOOCE, DUTCHMAN VAPORS, MOUNTAIN VAPORS, RUSTIC VAPORS. Associated Cases: 1:18-cv-00203-CRC, 1:18-cv-01615-CRC, 1:19-cv-00372-CRC(Wood, Jonathan)

1:18-cv-00203-CRC Notice has been electronically mailed to:

Damien M. Schiff dms@pacificlegal.org, incominglit@pacificlegal.org, tae@pacificlegal.org

Garrett Joseph Coyle garrett.coyle@usdoj.gov, fedprog.ecf@usdoj.gov

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ecc3478fca2ccd1df56d7d6148071d3721d7d467b90818b78d41ce7b830]]

Kiren Mathews

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Subject: Activity in Case 1:18-cv-00203-CRC JOOCE et al v. FOOD AND DRUG ADMINISTRATION et al Reply to opposition to Motion

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District of Columbia

Notice of Electronic Filing

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Case Name: JOOCE et al v. FOOD AND DRUG ADMINISTRATION et al
Case Number: 1:18-cv-00203-CRC
Filer: MOOSE JOOCE
DUTCHMAN VAPORS
MOUNTAIN VAPORS
RUSTIC VAPORS
Document Number: 31(No document attached)

Docket Text:
REPLY to opposition to motion re [26] MOTION for Partial Summary Judgment filed by MOOSE JOOCE, DUTCHMAN VAPORS, MOUNTAIN VAPORS, RUSTIC VAPORS. (ztd); (See docket entry no. [30] to view.)

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Jonathan Wood jwood@pacificlegal.org, incominglit@pacificlegal.org, telling@pacificlegal.org

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