UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MOOSE JOOCE, *et al.*, Plaintiffs, v. **FOOD AND DRUG ADMINISTRATION, *et al.*,** Defendants.	Case No. 18-cv-203 (CRC)
RAVE SALON, INC. d/b/a JOOSIE VAPES, Plaintiff, v. **FOOD AND DRUG ADMINISTRATION, *et al.*,** Defendants.	Case No. 18-cv-1615 (CRC)
JEN HOBAN d/b/a MASTERPIECE VAPORS, *et al.*, Plaintiffs, v. **FOOD AND DRUG ADMINISTRATION, *et al.*,** Defendants.	Case No. 19-cv-372 (CRC)

MEMORANDUM OPINION

Responding to the public health risks posed by dramatic increases in vaping, especially among teens, the Food and Drug Administration in 2016 exercised its statutory authority to

regulate electronic cigarettes.[1] It did so by issuing a final rule that deemed e-cigarettes to be "tobacco products" subject to regulation under the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) ("Tobacco Control Act"). As a result of this "Deeming Rule," e-cigarettes are now subject to all the same types of regulations as traditional cigarettes, including restrictions on advertising, a ban on sales to minors, and requirements for nicotine warnings on packaging and advertisements.

In these consolidated cases, a collection of e-cigarette manufacturers and retailers challenge the Deeming Rule under the Appointments Clause and the First Amendment of the U.S. Constitution. First, they contend that the rule violates the Appointments Clause because the FDA official who signed it was neither a Senate-confirmed "principal officer" nor a duly appointed and supervised "inferior officer." The Court will reject Plaintiffs' challenge. Since the Deeming Rule was issued, two Senate-confirmed FDA Commissioners have ratified it. These ratifications were effective and cured any potential Appointments Clause defect in the rule's issuance. Because it upholds the ratifications, the Court need not decide the merits of Plaintiffs' constitutional argument. Second, Plaintiffs argue that a pre-clearance requirement in the Tobacco Control Act now applicable to e-cigarettes violates the First Amendment because it places the burden on manufacturers to show that certain of their marketing claims are truthful and not misleading before they may make them. Since this case was filed, the D.C. Circuit issued an opinion in Nicopure Labs, LLC v. FDA, 944 F.3d 267 (D.C. Cir. 2019), on a

[1] This Opinion uses the term "e-cigarettes" to refer to all electronic nicotine delivery systems (ENDS) deemed to be tobacco products by the FDA, such as e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. See 81 Fed. Reg. 28,974, 29,028 (May 10, 2016); APP 306. These products include both "cigalikes," which mimic traditional cigarettes, and electronic devices that resemble everyday objects like flash drives.

substantially similar claim. The Court finds that Nicopure Labs directly controls the question raised here and requires dismissal of Plaintiff's First Amendment challenge.

I. Background

The Tobacco Control Act gives the Secretary of Health and Human Services authority to regulate four enumerated categories of tobacco products—namely "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco"—as well as "any other tobacco products that the Secretary by regulation deems to be subject to this subchapter." 21 U.S.C. § 387a(b). The HHS Secretary delegated this ability to "deem" tobacco products subject to the Act to the FDA Commissioner, who then sub-delegated that authority to the FDA's Assistant Commissioner for Policy ("ACP").[2] See 21 U.S.C. § 393(d)(2)(E) (permitting the HHS Secretary to delegate "such other functions as the Secretary may prescribe"); 2015 FDA Staff Manual Guide ("SMG") § 1410.10(1)(A)(14), J.A. 20 (delegation of authority to Commissioner); 2015 SMG § 1410.10(1)(A), J.A. 19 (delegation of authority to ACP). The HHS Secretary expressly "reserve[d] the authority to approve regulations of the FDA" that "establish procedural rules applicable to a general class" or "present highly significant public issues." 2015 SMG § 1410.10(2)(A), J.A. 20. The FDA Commissioner, in turn, reserved the power to "continue to exercise all delegated authority." 2012 SMG § 1410.21(1)(G)(1), J.A. 43; id. § 1410.21(1)(A), J.A. 40.

In 2014, the FDA issued a Notice of Proposed Rulemaking, signed by the ACP, seeking comments on its plan to deem all tobacco products, including e-cigarettes, subject to regulation

[2] The position has since been renamed the Associate Commissioner for Policy as a part of an agency reorganization. This Opinion will use "ACP" to refer to both the Assistant Commissioner and the Associate Commissioner as those positions had the same relevant responsibility, namely to promulgate rules for the FDA under the Tobacco Control Act.

under the Tobacco Control Act. 80 Fed. Reg. 23,141 (Apr. 25, 2014), J.A. 141. At least one of the Plaintiffs here submitted a comment to the FDA, arguing that the proposed rule did not take into account the positive benefits of e-cigarette use (or "vaping") and did not appropriately tailor the regulations to the retail vaping industry in light of those benefits. Dennisa Moore, Joosie Vapes Inc., Comment Letter on Proposed Rule Deeming Tobacco Products to be Subject to the FDCA as amended by the Family Smoking Prevention and Tobacco Control Act (Aug. 6, 2014), J.A. FDA 125272–74. None of the more than 135,000 commenters challenged the ACP's authority to sign the proposed or final rule.

The final Deeming Rule, also signed by the ACP, was issued two years later. 81 Fed. Reg. at 28,973–29,106, J.A. 252–384. In response to comments received on the proposed rule, the FDA considered "a robust body of scientific evidence about the uses and risks of e-cigarettes," Nicopure Labs, 944 F.3d at 273. This evidence included studies showing that e-cigarettes have the potential ability to help adults quit smoking conventional cigarettes, as well as studies indicating that young people who vape are more likely to begin smoking cigarettes. 81 Fed. Reg. at 29,036–41, J.A. 314–19. Balancing all the evidence, the FDA decided that risks of nicotine addiction for non-smoking youth outweighed the purported (and disputed) benefits of smoking cessation for adults. Id.

The Deeming Rule subjects e-cigarettes to the Tobacco Control Act and regulates their distribution, marketing, and labeling in two general ways: first, to reduce youth access, it bans sales to people under 18, requires ID checks for people under 26, and bans vending machine sales except in adult-only facilities, 81 Fed. Reg. at 29,057, J.A. 335; second, to inform consumers of the consequences of using the product, it requires packages and advertisements to contain a warning about the addictive nature of nicotine, 81 Fed. Reg. at 29,060, J.A. 338. In

addition, several provisions in the Tobacco Control Act and its implementing regulations automatically applied to e-cigarettes upon issuance of the final rule, such as regulations on misbranding, ingredient lists, and free samples. 81 Fed. Reg. at 29,051, J.A. 329. One provision now applicable to e-cigarettes specifically challenged here is the Tobacco Control Act's pre-clearance requirement for "modified risk products." The Act places the burden on a manufacture to show that a tobacco product "is safer than other tobacco products" before it may market it as such. The Act requires manufacturers "to substantiate such claims with evidence of their overall public health effects in advance of marketing, and to show that the proposed product as marketed will not mislead consumers as to its safety." Nicopure Labs, 944 F.3d at 284.

Since its issuance, the Deeming Rule has been ratified by two Senate-confirmed FDA Commissioners. In September 2016, FDA Commissioner Robert Califf ratified all of the agency's prior actions—including the Deeming Rule—as a part of a broad agency reorganization. J.A. 144. And after this litigation began, Commissioner Scott Gottlieb specifically ratified the Deeming Rule in April 2019. J.A. 231. He wrote:

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

Id.

According to Plaintiffs, between the time of the Rule's promulgation and the Commissioners' ratifications, several additional studies showed that e-cigarettes may help adults quit smoking cigarettes and reduce the adverse health effects of cigarettes. See Pls.' Opening Br. at 31–33 (citing studies). Other studies, Plaintiffs say, showed that certain regulations, which result in higher e-cigarette prices, have the effect of increasing the number of young people who

smoke conventional cigarettes. Id. at 34. Also during this interim period, the FDA issued guidance documents that have adjusted some of the compliance deadlines in the final rule. Id.

Three sets of plaintiffs filed suit against the FDA alleging that the ACP was not appointed consistent with the Appointments Clause and, therefore, that her execution of the notice of proposed rulemaking and the final rule requires the court to "set aside" the Deeming Rule. See, e.g., Moose Jooce Compl. ¶¶ 50–52 (quoting APA § 706(2)(A)). The parties have filed cross-motions for summary judgment on that issue. The Court held a hearing on October 22, 2019.

Plaintiffs also challenge the premarket review requirement for "modified risk tobacco products" under the First Amendment. See, e.g., Moose Jooce Compl. ¶¶ 54–57. The Court stayed briefing on that issue to await the D.C. Circuit's ruling on a substantially similar issue in Nicopure Labs. See Minute Order, June 8, 2018. After the D.C. Circuit decided that case in early December 2019, the Court asked the parties whether additional briefing was required. Plaintiffs responded that further briefing is necessary because the issue decided by the Circuit is distinguishable from the issues raised here, while the FDA maintained that the Circuit's opinion clearly forecloses Plaintiffs' First Amendment claim. See Joint Status Report ("JSR") (Dec. 17, 2019), ECF 42.

II. Legal Standards

Summary judgment may be granted when "there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Whether an agency action violates the Appointments Clause is a pure question of law that is properly decided 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); see also 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").

III. Analysis

A. The Appointments Clause

1. Forfeiture

As a threshold matter, the FDA contends that Plaintiffs forfeited their Appointments Clause challenge by not raising it during the rule's notice-and-comment period. Gov't's Cross-Mot. for Partial Summ. J. 18–20. They agency is correct that generally "a party must initially present its comments to the [relevant] agency during the rulemaking in order for the court to consider the issue," Tex Tin Corp. v. EPA, 935 F.2d 1321, 1323 (D.C. Cir. 1991), and that "[s]imple fairness . . . requires as a general rule that courts should not topple over administrative decisions unless the administrative body . . . has erred against objection made at the time" of its decision, Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin., 429 F.3d 1136, 1150 (D.C. Cir. 2005) (quoting United States v. L.A. Tucker Truck Lines, Inc., 344 U.S. 33, 37 (1952)). Appointments Clause claims are not immune from forfeiture. See, e.g., Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd., 574 F.3d 748, 755–56 (D.C. Cir. 2009) ("Intercollegiate I") (declining to consider an Appointments Clause challenge not raised in opening appellate brief).

But courts have discretion to consider an untimely objection in "rare cases." Freytag, 501 U.S. at 879 (explaining, in the context of an agency adjudication, that avoiding "the disruption to sound appellate process entailed by entertaining objections not raised below does not always overcome what Justice Harlan called 'the strong interest of the federal judiciary in maintaining the constitutional plan of separation of powers.'" (quoting Glidden Co. v. Zdanok, 370 U.S. 530,

535–536 (1962) (Harlan, J., plurality opinion))). The Court chooses it exercise its discretion here. Unlike the appellant in Intercollegiate I, Plaintiffs have offered a reason to "depart from [the] normal forfeiture rule" and have offered a strong "justification for its delay." 574 F.3d at 756. Rulemaking is different from adjudication. See Citizens Coal Council v. EPA, 447 F.3d 879, 904 n.25 (6th Cir. 2006) (noting that forfeiture rules "should not be applied freely in both" rulemaking and adjudication contexts, "given the fundamental differences between the two endeavors"). Even though the forfeiture rules may apply in both contexts, Styrene Info. & Research Ctr. v. Sebelius, 994 F. Supp. 2d 71, 79 (D.D.C. 2013), and parties surely can forfeit arguments not made before the agency during a comment period, see, e.g., Advocates for Highway & Auto Safety, 429 F.3d at 1150, the differences between rulemaking and adjudication counsel for a more lenient rule for unrepresented commenters who later wish to raise a separation-of-powers argument. Interested parties who are not attorneys or represented by counsel will naturally submit comments focusing on the rule's potential impact on them. It would be unfair to require them to raise esoteric legal arguments with the agency or else be prevented later from arguing them to a court, especially when those arguments relate to important separation-of-powers issues. Compare Intercollegiate I, 574 F.3d at 755–56 (applying forfeiture rules to a *represented* party who failed to raise its Appointments Clause challenge in an agency adjudication or its opening brief *in federal court*). Any prejudice to the agency pales in comparison to the unfairness to Plaintiffs, particularly considering the FDA can rectify any Appointments Clause problem through an effective ratification after litigation is commenced, see Part III.B., supra.

In the absence of any indication that Plaintiffs were represented during the comment period, see Mot. Hr'g Tr. 27:11–15 (Oct. 22, 2019) (rough), the Court will exercise its discretion to consider their Appointments Clause claim.

2. Ratification

a. Merits

Plaintiffs contend that the Deeming Rule is invalid because it was promulgated by an FDA employee who had not been properly appointed as an officer of the United States and therefore lacked authority under the Appointments Clause to issue binding agency rules. But the Deeming Rule was ratified by two different FDA Commissioners after its publication in May 2016, and the D.C. Circuit has repeatedly held that an agency's ratification of a prior decision or action cures any potential Appointments Clause violation if "a properly appointed official has the power to conduct an independent evaluation of the merits and does so." Intercollegiate Broad. Sys. v. Copyright Royalty Bd., 796 F.3d 111, 117 (D.C. Cir. 2015) ("Intercollegiate III") (citing FEC v. Legi-Tech, Inc., 75 F.3d 704 (D.C. Cir. 1996) and Doolin Security Savings Bank v. Office of Thrift Supervision, 139 F.3d 203 (D.C. Cir. 1998)); see also Wilkes-Barre Hospital Co. v. NLRB, 857 F.3d 364, 371 (D.C. Cir. 2017). It is the Plaintiffs' burden to present evidence—beyond the mere fact of ratification—"to suggest that the [agency] failed to conduct an independent evaluation of the merits or make a detached and considered judgment." Wilkes-Barre, 857 F.3d at 371 (internal quotation marks omitted). An "independent judgment" does not require the ratifier to "return to square one" of the administrative process. Rather, "the better course" for courts is to take the ratification "at face value and treat it as an adequate remedy" for an Appointments Clause violation. Legi-Tech, 75 F.3d at 708–09 (refusing to "forc[e] the [agency] to start at the beginning of the administrative process"). The test is akin to "harmless

error" under the APA. Doolin, 139 F.3d at 212–13 (explaining that the test for whether ratification is an adequate remedy "echoes the harmless error analysis" that "stems from the last sentence of § 706 of the Administrative Procedure Act: on judicial review of agency action, 'due account shall be taken of the rule of prejudicial error'"). Under this test, Plaintiffs bear the burden of providing evidence that the results of redoing the notice-and-comment process would yield a different result. Id.

In making that determination, the D.C. Circuit has instructed district courts not to look behind the ratification "notwithstanding the possibility" that it is merely a "rubberstamp" of the prior decision. Intercollegiate III, 796 F.3d at 118 n.1; see also Doolin, at 213 (holding that courts should find a ratification effective even if it has "misgivings" about whether there was a "real fresh deliberation"). To succeed, Plaintiffs must provide evidence of "continuing prejudice" of the alleged error after the ratification, "and whether that degree of prejudice—if it exists—requires dismissal." Legi-Tech, 75 F.3d at 708; see Intercollegiate III, 796 F.3d at 124 ("[T]he subsequent proceeding is constitutionally suspect only if there is sufficient continuing taint arising from the first."). The Circuit has also cautioned against examining internal agency deliberations regarding the ratification "absent a contention" that the ratifier was "actually biased." Legi-Tech, 75 F.3d at 709.

Plaintiffs argue that the highly deferential standard of review that the Circuit established for agency ratifications in the cases cited above, all of which involved enforcement actions or adjudications, does not apply in the context of rulemakings like the one at issue here. Pls.' Reply/Opp'n 19–22. Rulemakings should be treated differently, Plaintiffs say, because the APA's procedural rulemaking requirements, including notice and opportunity for comment, continue until the moment of ratification. Id. The Court is not persuaded. Plaintiffs offer no

reason—other than the existence of APA procedures—for differentiating between ratifications of rules and ratifications of enforcement decisions or agency adjudications. Adjudications are also covered by a host of APA procedures, yet the Circuit has applied its ratification doctrine to agency adjudications as well. See Intercollegiate III, 796 F.3d at 119. Up to that point, the Circuit had only approved ratifications in the enforcement context, but it rejected the notion that the type of agency proceeding mattered. Id. And it has since implied—though did not outright decide—that rulemaking ratifications should be treated the same way. See Guedes v. Bureau of Alcohol, Tobacco, Firearms and Explosives, 920 F.3d 1, 12 (D.C. Cir. 2019) (accepting the parties' agreement that the ratification was effective to cure an Appointments Clause problem with a rulemaking).

Further, all the district courts in this District that have confronted the issue have applied the Circuit's ratification doctrine to rulemakings and have not required agencies to undergo the entire APA notice-and-comment processes anew before upholding otherwise effective ratifications. These courts have consistently held that a rulemaking "that would otherwise be unlawful due to procedural or technical defects . . . can be cured through a subsequent lawful ratification of that action." Alfa Int'l Seafood v. Ross, No. 17-cv-31, 2017 WL 3738397, at *1 (D.D.C. June 22, 2017) (Mehta, J.) (explaining that the court would accept a general post-litigation "statement [from the agency] acknowledging that [it] would re-promulgate the Rule in the same manner, even if it were required to re-start the notice and comment process"); see also State Nat'l Bank of Big Spring v. Lew, 197 F. Supp. 3d 177, 179–80 (D.D.C. 2016) (Huvelle, J.) (rejecting the notion that a ratification of a rulemaking requires the agency to redo the full APA's notice-and-comment procedures because, "regardless of the type of administrative action, [D.C. Circuit] decisions have consistently declined to impose formalistic procedural requirements

before a ratification is deemed to be effective"); Huntco Pawn Holdings, LCC v. U.S. Dep't of Defense, 240 F. Supp. 3d 206, 232 (D.D.C. 2016) (Kollar-Kotelly, J.) (holding that that a ratification submitted to the court by a properly appointed official settles "any serious dispute that the Final Rule, as published, reflects the decisions of the agency with authority to promulgate it").

Here, the ratifications by both Commissioner Califf and Commissioner Gottlieb cured any potential Appointments Clause issue with the promulgation of the Deeming Rule.

First, both ratifying Commissioners made "a detached and considered judgment" of the Deeming Rule. See Wilkes-Barre, 857 F.3d at 371. Commissioner Gottlieb ratified the Deeming Rule explicitly "based on [his] careful review of the rule, [his] knowledge of its provisions, and [his] close involvement in policy matters relating to this rule and its implementation." J.A. 231. He stated that he made a detached and considered judgment, and Plaintiffs have not provided any evidence to the contrary. The Court must therefore take Commissioner Gottlieb's ratification "at face value." Legi-Tech, 75 F.3d at 709. And while perhaps a closer question, Commissioner Califf's blanket ratification also meets the standards set by the D.C. Circuit. In Wilkes-Barre, the Circuit approved of a ratification of all "the actions taken during the period in which the Board lacked a valid quorum," 857 F.3d at 271, which is substantially similar to Commissioner Califf's ratification of "any actions taken . . . which in effect involved the authorities delegated herein prior to the effective date of this delegation," J.A. 144. Plaintiffs' counsel correctly noted at the hearing that the inference of "independent judgment" was stronger in Wilkes-Barre because the ratifier was the same person—though now validly appointed—who took the original actions. See Mot. Hr'g Tr. 5:17–6:3 (Oct. 22, 2019) (rough). But again, the Circuit instructs that the independent judgment of the ratifiers should be

taken "at face value," unless a plaintiff provides contrary evidence. Legi-Tech, 75 F.3d at 709. That evidence must be something more than the mere fact that the decision is being ratified. As Plaintiffs have not met that burden, the Court will not look behind Commissioner's Califf's blanket ratification either.

Second, Plaintiffs have not met their burden to show that any Appointments Clause violation was prejudicial in the sense that redoing the administrative process would yield a different result.[3] Plaintiffs' primary contention of error is that neither of the ratifying Commissioners discussed certain studies that were published between the issuance of the Deeming Rule and the later ratifications. Pls.' MSJ 30–37. By failing to acknowledge these intervening studies, Plaintiffs argue, the Commissioners violated the basic APA rule requiring agencies to consider important aspects of the problem before them. But Plaintiffs conflate ratification doctrine with APA requirements prior to agency action. This explains why their principal reliance on Butte County v. Hogen, 613 F.3d 190, 194 (D.C. Cir. 2010), is misplaced. There, the Secretary of Interior issued a final decision to take into trust land on which an Indian tribe wished to conduct gaming operations based on a years-old legal opinion by the

[3] Citing Legi-Tech, Plaintiffs assert that a court must find that it is "virtually inconceivable" that a new administrative process would yield a different result before it could accept a ratification. Pls.' Mot. for Partial Summ. J. 30–31 ("Pls.' MSJ"); Pls.' Reply/Opp'n 25–27. But the Circuit did not create such a stringent test in Legi-Tech. In explaining why requiring an agency to redo the administrative process is not the correct remedy, the Circuit merely noted that "[e]ven were the Commission" to do so in that case, "it is virtually inconceivable that its decisions would differ in any way the second time from that which occurred the first time." Legi-Tech, 75 F.3d at 708 (citing cases that explain that "remand to the agency is an unnecessary formality where the outcome is clear"). The panel was merely explaining why, in light of "human nature," it would not generally be the case that the result of a redo of the administrative process would be different. Id. at 709. Based on that understanding, the Circuit held that "return[ing] to square one" is not required for an effective ratification. Id. at 708.

Department's Solicitor, while ignoring more recent evidence offered by the plaintiffs. The Circuit found that the Secretary had violated the APA by not considering relevant information *before* issuing his decision. See id. at 194–95. Butte County says little about the effectiveness of a ratification, however. Agency ratifications, which by definition come *after* a final action has been taken, are not governed by standard APA rules. As discussed, "regardless of the type of administrative action, [Circuit] decisions have consistently declined to impose formalistic procedural requirements before a ratification is deemed to be effective." State Nat'l Bank, 197 F. Supp. 3d at 184.

It bears noting that the effective ratification of the Deeming Rule does not prevent Plaintiffs from petitioning the FDA to repeal or amend the rule in light of the intervening studies. See 5 U.S.C. § 553(e) ("Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."); cf. CTS Corp. v. EPA, 759 F.3d 52, 65 (D.C. Cir. 2014) (denying review based on the inability to comment on post-promulgation studies being added to the final record because plaintiff "could have petitioned the EPA for either reconsideration or a new rulemaking, or to reopen the notice-and-comment period."). If Plaintiffs are not satisfied with the agency's response, they can seek judicial review. See id. §§ 702, 706; see also Shipbuilders Council of Am. v. United States, 868 F.2d 452, 456 (D.C. Cir. 1989) ("The denial of . . . a [section 553(e)] petition is subject to judicial review, provided that the petitioner can establish the requisite article III standing.").

In any case, the studies cited by Plaintiffs do not give the Court pause about whether a new notice-and-comment period would have yielded different results. See Doolin, 139 F.3d at

212–13.[4] The FDA considered studies that purported to show that e-cigarettes may be effective as smoking cessation devices and healthier in some respects than conventional cigarettes. But it nevertheless concluded that e-cigarettes "clearly have the potential to increase tobacco use and net health costs for the public as a whole." Nicopure Labs, 944 F.3d at 275 (citing 81 Fed. Reg. at 29,038). It is that ultimate conclusion which led the FDA to deem e-cigarettes subject to the Tobacco Control Act. Though the new studies Plaintiffs raise here may add to the quantum of evidence, there is no indication whatsoever that they alone would have upset the balance struck by the agency.

Finally, Plaintiffs have failed to show any "'continuing prejudice' from the [alleged] violations." Wilkes-Barre, 857 F.3d at 372 (quoting Legi-Tech, 75 F.3d at 708–09). The Court will not presume that any taint from the alleged Appointments Clause violation continued after the rule was ratified. Legi-Tech, 75 F.3d at 708. And there is no indication that either of the ratifiers were "biased" by the alleged improper promulgation of the rule. See Legi-Tech, 75 F.3d at 709; Wilkes-Barre, 857 F.3d at 372. Without such a showing, the Court may not look behind the decision-making process that led to the ratifications. It must take them "at face value and treat [them] as an adequate remedy" for any potential Appointments Clause violation. Legi-Tech, 75 F.3d at 709**.**

The Court therefore finds the ratifications effective.

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[4] Plaintiffs also cite the FDA's adjustment of compliance dates as evidence that a new rulemaking would yield a different result. Pls.' Reply/Opp'n 26–27. But while the Court does not discount the importance of compliance deadlines to the industry, that the FDA has extended them says little about whether it would reissue the substantive aspects of the rule.

b. Ratification is Resolution on the Merits

Plaintiffs contend that their Appointments Clause challenge survives even if the ratifications were effective. They argue that ratifications in actions challenging a rulemaking merely moot the case (rather than operate as a decision on the merits) and that the voluntary-cessation exception to mootness applies to the ratifications here. Pls.' MSJ 37–40. Plaintiffs maintain that because there is no guarantee that the FDA will not simply continue its purportedly illegal practice of having the ACP sign final rules, the Court retains jurisdiction notwithstanding the effectiveness of the ratifications.

Again, Plaintiffs run headlong into D.C. Circuit precedent. The 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 by remedying the defect (if any) from the initial appointment." Guedes v. Bureau of Alcohol, Tobacco, Firearms and Explosives, 920 F.3d 1, 13 (D.C. Cir. 2019) (cleaned up); see e.g., Wilkes-Barre, 857 F.3d at 371 (reaffirming that "[r]atification can remedy defects arising from the decisions of improperly appointed officials"). That rule make sense. Whether the FDA issues future rules through an improperly appointed officer is irrelevant to whether the Deeming Rule—the only rule challenged here—is valid. It is valid because it was ratified. Yet to be promulgated rules, that may or may not pose Appointments Clause concerns and may or may not affect these Plaintiffs, must await a different case. A challenge to them is too speculative in nature to be considered in this suit. Plaintiffs can (and should) raise potential Appointments Clause violations to the agency during such future rules' notice-and-comment periods to give the FDA the chance to confront any problems before they materialize.

Plaintiffs attempt to distinguish the well-established principle that ratification resolves Appointments Clause issues on the merits by highlighting that the relevant D.C. Circuit opinions all involved defenses to enforcement actions as opposed to independent, pre-enforcement challenges. Pls.' MSJ 37–38. That difference, to Plaintiffs, warrants rejecting the general rule and finding that the ratifications here merely moot their claim. Id. Plaintiffs primarily rely on the Guedes panel's discussion of ratification and mootness, id. (quoting Guedes, 920 F.3d at 12–17), but they read Guedes too far. That case involved President Trump's appointment of Acting Attorney General Whitaker under the Federal Vacancies Reform Act, after Attorney General Sessions resigned and before Attorney General Barr was nominated and confirmed. Guedes, 920 F.3d at 9. Although most of the rulemaking process at issue took place under General Sessions, it was Acting General Whitaker who signed the final rule. After General Barr was confirmed, he announced—similar to Commissioner Gottlieb here—that he had "independently reevaluate[d]" the rule and the "underlying rulemaking record" and that he "personally c[a]me to the conclusion that it is appropriate to ratify and affirm the final rule." Id. at 9. The Guedes plaintiffs conceded that the ratification was effective, and the Circuit held—on appeal of a denial of preliminary injunctive relief—that "with th[e] act of ratification and the concession, [the plaintiff's] likelihood of success on the merits of his challenge to the rule based on Acting Attorney General Whitaker's role in its promulgation *reduces to zero*." Id. at 12 (emphasis added). The ratification meant that the plaintiffs would be unable to succeed on the merits because the ratification resolved the merits of their pre-enforcement Appointments Clause challenge. Full stop. Admittedly, the panel went on to address in dicta why the claim still lacked a likelihood of success *even if* they were to adopt the proposed analytical approach that ratification merely moots a claim. Id. at 14–17. But the panel assuredly did not adopt that approach, and its belt-

and-suspenders mootness discussion does nothing to alter or undermine its fundamental holding, which this Court is bound to apply: Ratification resolves potential Appointments Clause errors on the merits. Id. at 13.

B. The First Amendment

Plaintiffs also challenge the rule under the First Amendment. E.g. Moose Jooce Compl. ¶¶ 54–57. They argue that the FDA's premarket review of e-cigarettes that purport to reduce harm or the risk of disease is an impermissible restriction on commercial speech because it puts the burden on speakers (*i.e.*, e-cigarette manufacturers) to prove that their marketing materials are truthful and not misleading. E.g. Moose Jooce Compl. ¶¶ 55–56. The Court stayed the briefing on the First Amendment arguments pending the D.C. Circuits ruling in a case raising almost identically arguments. Once the Circuit issued that ruling in early December 2019, see Nicopure Labs, 944 F.3d 267 (D.C. Cir. 2019), the Court sought the views of the parties on whether Plaintiffs' arguments were now foreclosed or required further briefing. The parties disagreed on how to proceed: Plaintiffs argued that further briefing is required, while Defendants argued that Nicopure Labs resolved Plaintiffs' arguments.

The Court concludes that Nicopure Labs forecloses Plaintiffs' First Amendment claim. Plaintiffs maintain that Nicopure Labs is distinguishable because it merely "give[s] FDA the power to prohibit truthful, non-misleading speech if such speech is determined not to significantly reduce harm or to benefit the general public health" but does not "address[] at all the constitutionality of the Act's placement of the burden of proof entirely on the manufacturer-speaker, which is the focus of Plaintiffs' First Amendment claim." JSR, at 5. The Court disagrees. The Circuit expressly held that "[p]lacing an obligation on a manufacturer to demonstrate that an e-cigarette is in fact safer before it may market it as such easily" passes First

Amendment scrutiny. Nicopure Labs, 944 F.3d at 284; see also id. at 288 (rejecting several industry arguments that it claimed FDA did not adequately considered because "[e]ach of those suggestions seeks to place the onus on the government, rather than the manufacturers"). The Circuit quite clearly held that placing the burden on manufacturers to substantiate their marketing claims does not violate the First Amendment. Bound by that precedent, the Court holds that the Tobacco Control Act's premarket review provisions do not impermissibly burden speech.

IV. Conclusion

For the foregoing reasons, the Court will deny Plaintiff's Motion for Partial Summary Judgement and grant the FDA's Cross-Motion for Partial Summary Judgment on the Appointments Clause claim. The Court will also, *sua sponte*, grant Summary Judgment for the FDA on Plaintiffs' First Amendment Claim. A separate Order shall accompany this memorandum opinion.

CHRISTOPHER R. COOPER
United States District Judge

Date: February 11, 2020