No. 20-1203

In the Supreme Court of the United States

MOOSE JOOCE, ET AL., PETITIONERS

v.

FOOD AND DRUG ADMINISTRATION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether the court of appeals correctly held that the ratification of a final rule by the Commissioner of the Food and Drug Administration cured any alleged deficiency in connection with the appointment of the agency official who originally signed the rule.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. A1-A10) is reported at 981 F.3d 26. The opinion of the district court (Pet. App. B1-B22) is not published in the Federal Supplement but is available at 2020 WL 680143.

JURISDICTION

The judgment of the court of appeals was entered on December 1, 2020. The petition for a writ of certiorari was filed on February 26, 2021. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. a. The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or Act), Pub. L. No. 111-31, Div. A, 123 Stat. 1776 (21 U.S.C. 387 *et seq.*), established a comprehensive scheme for the regulation of tobacco products and gave the Secretary of Health and Human Services (HHS), through the U.S. Food and

Drug Administration (FDA), authority over such regulation. Congress made the Act's requirements immediately applicable to four types of tobacco products, including conventional cigarettes and smokeless tobacco, and it authorized the Secretary to bring within the scope of the Act's requirements "any other tobacco products that the Secretary by regulation deems to be subject to this chapter." 21 U.S.C. 387a(b). The Act defines "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. 321(rr)(1).

b. In a final rule issued in May 2016, FDA exercised its authority under Section 387a(b) to deem all products that meet the statutory definition of "tobacco product," except for accessories of such products, to be subject to the Tobacco Control Act's requirements. 81 Fed. Reg. 28,973, 28,975 (May 10, 2016). The rule took effect in August 2016, 90 days after its publication. *Id.* at 28,974.

In promulgating this "deeming rule," FDA brought products falling within the statutory definition of tobacco products, including cigars, pipe tobacco, and e-cigarettes, under the comprehensive regulatory scheme established by Congress. See 81 Fed. Reg. at 28,976; see also *id.* at 28,993-28,994 (explaining "that the FDA has authority under the Tobacco Act to regulate electronic cigarettes") (quoting *Sottera, Inc.* v. *Food & Drug Admin.*, 627 F.3d 891, 898 (D.C. Cir. 2010)). Products newly deemed subject to the Act's various requirements thus must comply with provisions regarding, among other things, premarket review for new tobacco

products, health warnings on product packages and advertisements, and minimum-age sale restrictions. See *id.* at 28,976. FDA explained that, by bringing all tobacco products within the regulatory scheme established by Congress, the "deeming rule affords FDA additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use." *Id.* at 28,975. Among other benefits, the rule will enable FDA "to obtain critical information regarding the health risks of newly deemed tobacco products, including information derived from ingredient listing submissions and reporting of harmful and potentially harmful constituents." *Ibid.* The rule will also "prevent from entering the market new tobacco products that are not appropriate for the protection of public health." *Ibid.*

c. Before the deeming rule was issued, the Secretary delegated rulemaking authority to the FDA Commissioner. C.A. App. 189 (2015 FDA Staff Manual Guides § 1410.10(1)(A)(14)). The FDA Commissioner in turn delegated to the Associate Commissioner for Policy the authority to "perform any of the functions of the Commissioner with respect to the issuance of [Federal Register] notices and proposed and final regulations of the Food and Drug Administration," *id.* at 41 (2012 FDA Staff Manual Guides § 1410.21(1)(G)(1)); see Pet. App. G6. The FDA Commissioner expressly retained power "to exercise all delegated authority," C.A. App. 38 (2012 FDA Staff Manual Guides § 1410.21(1)(A)), and the Secretary reserved the authority "to approve regulations of FDA" that "[p]resent highly significant public issues," *id.* at 196 (2015 FDA Staff Manual Guides § 1410.10(2)(A)(2)).

Both the notice of proposed rulemaking and the final deeming rule were signed by Leslie Kux, who served as

FDA's Associate Commissioner for Policy. 81 Fed. Reg. at 29,106; 79 Fed. Reg. 23,142, 23,207 (Apr. 25, 2014).[1] Ms. Kux is a member of the Senior Executive Service and was appointed to the position now known as Associate Commissioner for Policy in 2012 by then-Secretary Kathleen Sebelius, with the concurrence of the then-Commissioner of FDA. See C.A. App. 36-37. Like other members of the Senior Executive Service within FDA, the Associate Commissioner for Policy could be removed from her role by the FDA Commissioner, subject to the concurrence of the Secretary. *Id.* at 25 (2005 FDA Staff Manual Guide § 1431.23(1)(C)); see 5 U.S.C. 3131(5) ("The Senior Executive Service shall be administered so as to * * * enable the head of an agency to reassign senior executives to best accomplish the agency's mission[.]"). FDA's Deputy Commissioner for Policy, Legislation, and International Affairs can remove the Associate Commissioner from the Senior Executive Service altogether "for deficient performance." C.A. App. 26 (2005 FDA Staff Manual Guides § 1431.23(1)(H)); see 5 U.S.C. 3592 (statutory standards for removal from the Senior Executive Service).

d. When the deeming rule was promulgated, both the HHS Secretary and the FDA Commissioner expressed their approval of the rule. News Release, FDA, U.S. Dep't of Health & Human Servs., *FDA Takes Significant Steps to Protect Americans from Dangers of Tobacco Through New Regulation* (May 5, 2016), https://go.usa.gov/xvvPC (recounting the Secretary's

[1] At the time of the notice of proposed rulemaking, the position of Associate Commissioner for Policy was called the Assistant Commissioner for Policy. The position was renamed in 2014 as part of an agency reorganization. See C.A. App. 182.

statement that increased "use of other nicotine products, including e-cigarettes * * * is creating a new generation of Americans who are at risk of addiction" and that the deeming rule's "announcement is an important step in the fight for a tobacco-free generation" that will help FDA "put into place rules that protect our kids and give adults information they need to make informed decisions"); C.A. App. 198-201. After the deeming rule was issued, FDA Commissioners have twice formally ratified it.

First, in September 2016 as part of an agency reorganization, then-FDA Commissioner Robert M. Califf ratified and affirmed all "actions taken by [FDA officials] or [their] subordinate(s), which in effect involved the exercise of the authorities delegated herein prior to the effective date of this delegation." Pet. App. G16. That ratification included the deeming rule.

Second, in April 2019, then-FDA Commissioner Scott Gottlieb specifically ratified the deeming rule. Noting that "[t]he authority under which the Deeming Rule was issued has been questioned in litigation," Commissioner Gottlieb "affirm[ed] and ratif[ied] 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." Pet. App. F1. Commissioner Gottlieb stated that he undertook the ratification "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, as well as its public health importance." *Ibid.* Commissioner Gottlieb also stated that his action was "not intended to suggest any legal defect or infirmity in the promulgation of the Deeming Rule." *Ibid.*

2. a. Petitioners are e-cigarette manufacturers and retailers, and a non-profit organization that promotes e-cigarette use. Pet. App. A2. Petitioners filed three separate suits alleging that the Associate Commissioner for Policy is a principal officer who was not appointed consistent with the requirements of the Appointments Clause, U.S. Const. Art. II, § 2, Cl. 2, and that the deeming rule was therefore invalidly issued. See Pet. App. B7. The United States District Court for the District of Columbia consolidated the actions and granted summary judgment for FDA, concluding that "the ratifications by both Commissioner Califf and Commissioner Gottlieb cured any potential Appointments Clause issue with the promulgation of the Deeming Rule." *Id.* at B14. The court did not address the government's arguments that petitioners' Appointments Clause argument failed because Associate Commissioner Kux was a validly appointed inferior officer when she signed the deeming rule. See D. Ct. Doc. 28-1, at 28-38 (June 6, 2019).

b. A unanimous panel of the court of appeals affirmed. Pet. App. A2. Like the district court, the court of appeals did not reach the government's argument that Associate Commissioner Kux's issuance of the deeming rule did not violate the Appointments Clause, instead holding only that "Commissioner Gottlieb's ratification cured any Appointments Clause defect." *Id.* at A6; see Gov't C.A. Br. 31-38. The court explained that "[r]atification occurs when a principal sanctions the prior actions of its purported agent." Pet. App. A5 (citation omitted). The D.C. Circuit "has repeatedly recognized that ratification can remedy a defect arising from the decision of an improperly appointed official, such as the alleged defect arising from the issuance of

the Deeming Rule by Associate Commissioner for Policy Kux." *Ibid.* (citing *Wilkes-Barre Hosp. Co., LLC* v. *NLRB*, 857 F.3d 364, 371 (D.C. Cir. 2017), and *Intercollegiate Broad. Sys., Inc.* v. *Copyright Royalty Bd.*, 796 F.3d 111, 117-121, 124 (D.C. Cir. 2015)).

Relying on longstanding circuit precedent, the court of appeals rejected petitioners' argument that Commissioner Gottlieb lacked authority to ratify the deeming rule after petitioners filed suit, as well as their contention that it was arbitrary and capricious for the Commissioner to ratify the rule without considering new evidence not in the rulemaking record Pet. App. A6-A7. The court also noted that "nothing in the record indicates that Commissioner Gottlieb, when he ratified the Deeming Rule, failed to conduct an independent evaluation of the merits, or to make a detached and considered judgment." *Id.* at A7-A8 (citation and internal quotation marks omitted). Given its affirmance based on Commissioner Gottlieb's ratification, the court declined to address the effect of Commissioner Califf's earlier ratification. *Id.* at A8.

The court of appeals also rejected petitioners' argument that "Appointments Clause violations are *per se* harmful, not curable by ratification," noting its previous rejection of arguments that "prejudice must be presumed for Appointments Clause violations," or that "'speculative taint'" like "the possibility that an invalid action was subsequently affirmed 'simply out of agency solidarity'" sufficed. Pet. App. A8-A9 (citation omitted). The court found that petitioners "demonstrate[d] no continuing prejudice" and concluded that, "[a]bsent record evidence of continuing prejudice, the court will take Commissioner Gottlieb's ratification 'at face value and treat it as an adequate remedy.'" *Id.* at A9 (quoting

Wilkes-Barre Hosp., 857 F.3d at 372). The court also rejected petitioners' argument, not presented in the petition for a writ of certiorari, that provisions of the Tobacco Control Act violate the First Amendment. *Id.* at A10.

ARGUMENT

The decision of the court of appeals is correct and does not conflict with any decision of this Court or another court of appeals. Consistent with well-established principles of agency law, the D.C. Circuit has, over several decades, "repeatedly held that a properly appointed official's ratification of an allegedly improper official's prior action * * * resolves the claim on the merits by remedy[ing] [the] defect (if any) from the initial appointment." *Guedes* v. *Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 13 (2019) (per curiam), cert. denied, 140 S. Ct. 789 (2020) (citation and internal quotation marks omitted; brackets in original). The court's conclusion that the FDA Commissioner properly ratified the deeming rule is a straightforward application of that longstanding rule. Petitioners are incorrect in asserting that there is a division in authority regarding this common-sense approach, and in any event, this case would be a poor vehicle for considering petitioners' contentions in favor of a different rule, given that this issue would be unlikely to affect the outcome in this case. Further review is not warranted.

1. The court of appeals correctly held that "Commissioner Gottlieb's ratification * * * cured any potential Appointments Clause defect arising from Associate Commissioner for Policy Kux's issuance of the Deeming Rule." Pet. App. A9-A10.

a. The Appointments Clause generally requires that "Officers of the United States" be appointed by the

President "'by and with the Advice and Consent of the Senate,'" but "Congress may vest the appointment of 'inferior Officers' in 'the President alone,' 'Courts of Law,' and 'the Heads of Departments.'" *Guedes*, 920 F.3d at 11 (quoting U.S. Const. Art. II, § 2, Cl. 2). All officers, both principal and inferior, can wield "significant authority pursuant to the laws of the United States," *Buckley* v. *Valeo*, 424 U.S. 1, 126 (1976) (per curiam), including rulemaking power. See *id.* at 140-141. Thus, the exercise of "significant authority," such as rulemaking, does not "mark[] * * * the line between principal and inferior officer"; rather, it marks "the line between officer and nonofficer." *Edmond* v. *United States*, 520 U.S. 651, 662 (1997) (citation omitted); see *Lucia* v. *SEC*, 138 S. Ct. 2044, 2051 (2018). Whether an officer is "principal" or "inferior" depends instead on whether the officer "has a superior," such that her "work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Edmond*, 520 U.S. at 662-663.

At the time she signed the deeming rule, Ms. Kux was properly appointed by the HHS Secretary as an inferior officer whose work was directed and supervised by the FDA Commissioner and the Secretary. See C.A. App. 36-37. The Commissioner and Secretary had authority to remove Ms. Kux from her role as Associate Commissioner, and they themselves retained rulemaking authority. Moreover, nothing precluded the Secretary or the FDA Commissioner from rescinding the Associate Commissioner for Policy's delegated rulemaking authority at any time. See *In re Sealed Case*, 829 F.2d 50, 56 (D.C. Cir. 1987) (noting an officer's ability to rescind a delegation of authority), cert. denied, 484 U.S.

1027 (1988); C.A. App. 189 (2015 FDA Staff Manual Guides § 1410.10(1)(A)(14)); C.A. App. 38 (2012 FDA Staff Manual Guides § 1410.21(1)(A)). Because Associate Commissioner Kux was a validly appointed inferior officer, and not a principal officer as petitioners contend, there was no Appointments Clause defect in the authority under which the deeming rule was issued. In light of their conclusion that at least one of the two subsequent ratifications by FDA Commissioners cured any appointment defect, neither the district court nor the court of appeals found it necessary to address the government's Appointments Clause arguments. But this ground would provide an independent basis for affirming the judgment in this case.

b. Even assuming there existed an Appointments Clause problem that created some defect in FDA's issuance of the deeming rule, the court of appeals correctly concluded that Commissioner Gottlieb cured any such defect by ratifying the rule's promulgation.

When an agent lacks authority to act on behalf of a principal, the principal (acting on its own or through a valid agent) may subsequently authorize actions that were taken by the agent who lacked authority. Restatement (Third) of Agency Ch. 4, intro. note (2006); *id.* § 4.01 cmt. b; see *United States* v. *Heinszen & Co.*, 206 U.S. 370, 382 (1907). Such a ratification has retroactive effect: it "operates upon the act ratified in the same manner as though the authority of the agent to do the act existed originally." *Marsh* v. *Fulton Cnty.*, 77 U.S. (10 Wall.) 676, 684 (1871); accord *Heinszen & Co.*, 206 U.S. at 382 (stating that ratification "retroactively give[s]" an agent's acts "validity"). This Court has indicated that agency-law principles of ratification presumptively apply to governmental actions that were not

properly authorized when they were taken. *Federal Election Comm'n* v. *NRA Political Victory Fund*, 513 U.S. 88, 98 (1994) (stating that whether a later governmental authorization rendered valid an unauthorized filing was "at least presumptively governed by principles of agency law, and in particular the doctrine of ratification"); see *Heinszen & Co.*, 206 U.S. at 382 (describing it as "elementary" that "the power of ratification as to matters within their authority may be exercised by Congress, state governments or municipal corporations").

Consistent with those decisions, the D.C. Circuit "has repeatedly recognized that ratification can remedy a defect arising from the decision of an improperly appointed official, such as the alleged defect arising from the issuance of the Deeming Rule by Associate Commissioner for Policy Kux." Pet. App. A5 (citing *Wilkes-Barre Hosp. Co., LLC* v. *NLRB*, 857 F.3d 364, 371 (D.C. Cir. 2017), and *Intercollegiate Broad. Sys., Inc.* v. *Copyright Royalty Bd.*, 796 F.3d 111, 117–121, 124 (D.C. Cir. 2015)). As the court of appeals explained, "[r]atification occurs when a principal sanctions the prior actions of its purported agent." *Ibid.* (quoting *Doolin Sec. Sav. Bank, F.S.B.* v. *Office of Thrift Supervision*, 139 F.3d 203, 212 (D.C. Cir. 1998) (citing Restatement (Second) of Agency § 82 (1958)), superseded on other grounds by statute, Federal Vacancies Reform Act of 1998, Pub. L. No. 105-277, 112 Stat. 2681 (5 U.S.C. 3345 *et seq.*)).

The court of appeals correctly applied these principles to conclude that Commissioner Gottlieb's ratification of the deeming rule rendered it validly promulgated, even assuming any appointment defect attended

its original issuance. There is no dispute as to the nature of the relationship between the relevant actors here: the Associate Commissioner for Policy acts as the agent of the FDA Commissioner in performing her duties. And there is likewise no question that, notwithstanding the delegation of rulemaking authority to the Associate Commissioner for Policy, the Commissioner can properly exercise FDA rulemaking authority, and thus could have issued the deeming rule in the first instance. Accordingly, under ordinary agency-law principles, Commissioner Gottlieb's ratification rendered the rule's earlier promulgation valid even if Associate Commissioner Kux originally lacked authority to approve its promulgation.

2. Petitioners contend (Pet. 16-23) that the court of appeals' straightforward application of these principles conflicts with decisions of this Court and the Ninth Circuit. That contention lacks merit; there is no division in authority requiring this Court's attention. This Court has previously declined to entertain similar arguments, see *Gordon* v. *Consumer Fin. Prot. Bureau*, 137 S. Ct. 2291 (2017) (No. 16-673), and it should follow the same course here.

a. Petitioners first contend (Pet. 16) that the court of appeals' decision in this case fails to give effect to the rule articulated in *NRA Political Victory Fund* that effective ratification requires a principal to have authority to do the act being ratified both at the original time and at the time of ratification. See 513 U.S. at 98. In that case, the Federal Election Commission (FEC) had filed a petition for a writ of certiorari within the 90 days provided by statute, 28 U.S.C. 2101(c), but the petition was not authorized by the Solicitor General during that period, see 28 C.F.R. 0.20(a) (1994). More than 120 days

after the petition was filed, the Solicitor General sent a letter stating that he authorized the petition's filing, but the time for filing a petition had by that time expired. *NRA Political Victory Fund*, 513 U.S. at 98. The case thus presented the question whether an official could ratify an action he no longer had authority to perform. This Court explained that, "[i]f an act to be effective in creating a right against another or to deprive him of a right must be performed before a specific time, an affirmance is not effective against the other unless made before such time." *Ibid.* (quoting Restatement (Second) of Agency § 90). The Court observed that a contrary holding would essentially give the ratifying official "unilateral power to extend the" deadline. *Id.* at 99. Accordingly, because the Solicitor General lacked authority to file a certiorari petition after the deadline had passed, he could not ratify the FEC's decision to file at that time. *Id.* at 98.

The D.C. Circuit's decision in this case is consistent with *NRA Political Victory Fund*. The court of appeals quoted petitioners' argument that the party ratifying "should be able not merely to do the act ratified at the time the act was done, *but also at the time the ratification was made*," but concluded that Commissioner Gottlieb's ratification was consistent with that proposition. Pet. App. A7 (quoting *NRA Political Victory Fund*, 513 U.S. at 98). And unlike in *NRA Political Victory Fund*, the Tobacco Control Act imposes no time limits on FDA's rulemaking authority, and the agency was not constrained to take action by a fixed deadline. The FDA Commissioner thus had rulemaking authority in connection with the deeming rule at both the time the rule was issued and the time at which it was ratified.

Petitioners do not suggest otherwise, instead urging that the D.C. Circuit has previously erred in focusing on the lack of time constraints on a ratifying official's authority rather than looking at limitations on authority more broadly. See Pet. 16-18 (discussing *Doolin*, 139 F.3d at 213). But the Tobacco Control Act has no restrictions—temporal or otherwise—that limited Commissioner Gottlieb's power to issue the deeming rule at the time of the ratification. The distinction petitioners propose to draw between timing limitations and other constraints on agency authority is thus irrelevant to this case.

b. Contrary to petitioners' argument (Pet. 22-23), there is likewise no tension between the court of appeals' decision in this case and *Consumer Financial Protection Bureau* v. *Gordon*, 819 F.3d 1179 (9th Cir. 2016), cert. denied, 137 S. Ct. 2291 (2017). In *Gordon*, the Ninth Circuit considered whether ratification of a Consumer Financial Protection Bureau (CFPB) enforcement action could cure an Appointments Clause defect underlying the original charging decision. The plaintiffs argued that the CFPB Director, once properly appointed, could not ratify a decision he made at a time when he was not properly appointed. See *id.* at 1191.

The Ninth Circuit rejected that argument, expressly "agree[ing] with the D.C. Circuit's approach" to ratification. *Gordon*, 819 F.3d at 1191 (citing *Doolin*, 139 F.3d at 212-213). In accordance with that approach, the Ninth Circuit held that "[b]ecause the CFPB," the principal, "had the authority to bring the action at the time Gordon was charged, [the Director's] August 2013 ratification, done after he was properly appointed as Director, resolves any Appointments Clause deficiencies." *Id.* at 1192. Similarly, here FDA undoubtedly had the

authority to issue the deeming rule in 2016 when it was promulgated, and the FDA Commissioner, who retains power with respect to rulemaking, had the necessary authority at the time he ratified the rule.

c. Petitioners urge (Pet. 18-19) a significant addition to the ratification principles articulated by this Court and reflected in court of appeals cases, asserting that this Court should create a requirement specific to the rulemaking context that a ratifying official must essentially reopen the rulemaking process before ratifying. They contend (Pet. 19) that the D.C. Circuit should have "review[ed] Commissioner Gottlieb's attempted ratification on the assumption that the Deeming Rule had never been issued, that the rulemaking record therefore had not closed, and accordingly that the Commissioner was obliged to take into account all of the relevant data available to him up to" the point of ratification.[2]

Ratification on those terms, however, would not be ratification at all; it would constitute a new rulemaking. The D.C. Circuit has long rejected the notion that an

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[2] Amicus Cato Institute suggests that in the rulemaking context, courts are obliged to order the equivalent of the "new hearing" that may be appropriate to remedy agency adjudications conducted by an official acting in violation of the Appointments Clause. See Cato Amicus Br. 4-7 (quoting *Lucia*, 138 S. Ct. at 2055). But it does not identify any rulemaking procedures beyond the notice-and-comment process, which the agency undisputedly had already conducted. Petitioners do not contend that the notice-and-comment process FDA undertook was constitutionally invalid, nor do they embrace other amici's theory that even providing public notice of a proposed rule is void and must be redone if issued by an improperly appointed officer. See Nat'l & State Electronic Nicotine Delivery Sys. Prod. Advocacy Ass'ns Amicus Br. 18-19. Rather, petitioners urge (Pet. 18-20) only that the Commissioner was required to consider comments and evidence submitted after the completed comment period.

agency "must repeat the entire administrative process" in order for ratification to be effective. *Federal Election Comm'n* v. *Legi-Tech, Inc.*, 75 F.3d 704, 708 (1996); see *Doolin*, 139 F.3d at 214 (confirming that an agency is not required to "redo[] the administrative proceedings" in order for ratification to be effective); see also *Gordon*, 819 F.3d at 1192 (citing *Legi-Tech* with approval for the conclusion that "a newly constituted FEC need not 'start at the beginning' and 'redo the statutorily required procedures in their entirety'") (citing *Legi-Tech*, 75 F.3d at 707, 709). The court of appeals here applied that longstanding and generally applicable rule, and petitioners cite no case endorsing the novel rulemaking-ratification regime they propose.

Moreover, petitioners improperly conflate the question of ratification with arbitrary-and-capricious review. See Pet. 19-20 & n.17. Consistent with principles of administrative law, the reasonableness of agency action is assessed on the administrative record, comprised of contemporaneous materials considered by the agency at the time of its decision. See *Appalachian Power Co.* v. *EPA*, 249 F.3d 1032, 1059 (D.C. Cir. 2001) (per curiam) (agency does not act "arbitrarily and capriciously" in "ignor[ing]" comments and evidence "not timely filed" during the notice-and-comment rulemaking process).

To the extent petitioners suggest that Commissioner Gottlieb should have selectively considered certain studies published after the comment period closed in order to authorize the deeming rule as of May 2016, they misstate the basic principles that govern agency rulemakings. To the extent that petitioners instead urge that Commissioner Gottlieb was required to undertake a new rulemaking process with a new administrative

record updated through April 2019, they misapprehend the nature of ratification. A ratification is not a new action, but the "subsequent adoption and affirmance by one person of an act which another, without authority, has previously assumed to do for him." Floyd R. Mechem, *A Treatise on the Law of Agency* § 347, at 260 (2d ed. 1914); see *Advanced Disposal Servs. E., Inc.* v. *NLRB*, 820 F.3d 592, 602 (3d Cir. 2016) (noting that a ratification "relates back in time to the date of the act by the agent") (citation and internal quotation marks omitted). Ratification "operates upon the act ratified in the same manner as though the authority of the agent to do the act existed originally." *Marsh*, 77 U.S. (10 Wall.) at 684. Here, as the court of appeals explained, "the rulemaking record closed in 2016 and consequently Commissioner Gottlieb had no * * * obligation to consider new evidence in 2019." Pet. App. A7.

d. There is likewise no support for petitioners' suggestion (Pet. 20-21) that the Court adopt a rule that Appointments Clause defects may never be cured through ratification. According to petitioners, "an Appointments Clause violation" means that "there is no valid principal-agent relationship that can sustain a ratification." Pet. 21.

This argument misapprehends the relevant agency principles. The basic premise of ratification is that a principal may adopt and affirm an action that someone "purporting to act" on his behalf, "*without authority*, has previously assumed to do for him." Mechem § 347, at 260 (emphasis added). It is the original actor's very lack of authority—whether stemming from an Appointments Clause defect or some other cause—that provides the occasion for subsequent ratification by the

principal. Accordingly, courts have concluded that ratification can indeed cure appointment-related defects in the administrative context. See, *e.g.*, *Guedes*, 920 F.3d at 12; *Advanced Disposal Servs.*, 820 F.3d at 602-606; *Gordon*, 819 F.3d at 1190-1192; *Intercollegiate*, 796 F.3d at 117-119.

In accordance with this precedent, the court of appeals correctly rejected petitioners' argument that "Appointments Clause violations are *per se* harmful, not curable by ratification," explaining that Commissioner Gottlieb had already remedied any such defect here by "effectively ratif[ying] the Deeming Rule." Pet. App. A8-A9. The FDA Commissioner—who had authority to approve final rules in both 2016 and 2019—made clear after "careful review of the rule" that he would have made the same decision, consistent with his predecessor's and the HHS Secretary's contemporaneous statements in support of that rule. *Id.* at A6; see pp. 4-5, *supra* (discussing FDA's 2016 press release); Pet. App. A7-A8 (explaining that "nothing in the record indicates that Commissioner Gottlieb * * * failed to conduct an independent evaluation of the merits * * * or to make a detached and considered judgment") (citations and internal quotation marks omitted).

Nor is there any "record evidence of continuing prejudice" stemming from the absence of the reopened notice-and-comment process petitioners seek. Pet. App. A9. The court of appeals observed that the preamble to the deeming rule expressly acknowledged that "there was uncertainty about the health effects of e-cigarettes," and it was nonetheless the agency's now-ratified conclusion "that the regulation of e-cigarettes 'will still benefit public health' even if," as petitioners

contend has now occurred, "e-cigarettes 'may eventually be shown to have a net benefit on or harm to public health at the population level.'" *Ibid.* (quoting 81 Fed. Reg. at 28,984). In such circumstances, the court correctly refused to rely on "speculative taint" that the ratification was disingenuous, and instead "t[ook] Commissioner Gottlieb's ratification 'at face value and treat[ed] it as an adequate remedy'" for the alleged Appointments Clause violation. *Ibid.* (quoting *Intercollegiate Broad.*, 796 F.3d at 124, and *Wilkes-Barre Hosp.*, 857 F.3d at 372).[3]

3. Even assuming that the well-established ratification principles applied by the court of appeals here might warrant this Court's review on some occasion, this case would be a poor vehicle for addressing them. Petitioners' arguments regarding ratification, even if correct, would be unlikely to affect the outcome in this case. As the government urged below, Associate Commissioner Kux's exercise of delegated authority with respect to the deeming rule was entirely consistent with the Appointments Clause. See Gov't C.A. Br. 31-38; D. Ct. Doc. 28-1, at 28-38. Neither the district court nor the court of appeals reached those arguments, which provide an independent basis to deny petitioners relief. See pp. 8-10, *supra*.

Similarly, as the district court found, even if an Appointments Clause defect existed, Commissioner

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[3] Several Members of Congress acting as amici assert that the court of appeals' decision here gives insufficient weight to the political-accountability principles protected by the Appointments Clause. See Senators' Amicus Br. 9-13. But permitting ratification fully accords with those principles, as it entails politically accountable officers assuming responsibility for decisions made by their subordinates.

Califf's September 2016 ratification independently cured any such defect. See Pet. App. B14-B15. Petitioners appear to acknowledge that at least part of their argument does not apply to this earlier ratification. See Pet. 19 n.16 (suggesting that in September 2016, Commissioner Califf could "reasonably have assumed, consistent with the APA, that the record assembled as of May, 2016, was still comprehensive"). While petitioners are incorrect that the APA's requirements affected the validity of Commissioner Gottlieb's ratification, their concession regarding the scope of the administrative record at the time of Commissioner Califf's ratification makes it even more unlikely that they could obtain relief in this case.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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