United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued September 23, 2020 Decided December 1, 2020

No. 20-5048

MOOSE JOOCE, ET AL.,
APPELLANTS

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLEES

Consolidated with 20-5049, 20-5050

Appeals from the United States District Court
for the District of Columbia
(No. 1:18-cv-00203)
(No. 1:18-cv-01615)
(No. 1:19-cv-00372)

Jonathan Wood argued the cause for appellants. With him on the briefs were *Damien M. Schiff* and *Oliver Dunford.*

Lindsey Powell, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Mark B. Stern* and *Joshua Revesz*, Attorneys, *Robert P. Charrow*, General Counsel, U.S. Department of Health and

Human Services, and *Peter G. Dickos*, Associate Chief Counsel, Food and Drug Administration.

Before: ROGERS and PILLARD, *Circuit Judges*, and SENTELLE, *Senior Circuit Judge*.

Opinion of the Court by *Circuit Judge* ROGERS.

ROGERS, *Circuit Judge*: Less than a year ago, the court rejected three challenges by an e-cigarette manufacturer and distributor, and an e-cigarette industry group to a rule deeming 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) ("the Act"). In *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 271 (D.C. Cir. 2019), the court held that it was "entirely rational and nonarbitrary [for the Food and Drug Administration ("FDA")] to apply to e-cigarettes the Act's baseline requirement that, before *any* new tobacco product may be marketed, its manufacturer show the FDA that selling it is consistent with the public health." The court also rejected First Amendment objections to the Act's barring of claims that e-cigarettes are safer than existing products absent such a demonstration and ban on the distribution of free e-cigarette samples. *Id*. at 272. Now other e-cigarette manufacturers and retailers, and a nonprofit organization focused on tobacco harm reduction raise two constitutional challenges to the rule. Under this court's precedents, their Appointments Clause challenge lacks merit and their First Amendment challenge is foreclosed. Accordingly, we affirm the grant of summary judgment to the FDA.

I.

The Act authorizes the Secretary of the Department of Health and Human Services to regulate the manufacture, sale, and distribution of tobacco products. It permits the Secretary to deem products to be "tobacco products" subject to the Act's requirements. 21 U.S.C. § 387a(b) (2018). One such requirement is the preclearance pathway for manufacturers seeking to market a "modified risk tobacco product," defined as "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." *Id.* § 387k(b)(1). Under the Act, a modified risk tobacco product may be commercially marketed only if the Secretary determines that the manufacturer has demonstrated that the product, as actually used by consumers, meets two requirements. *Id.* § 387k(g)(1). First, the product will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users." *Id.* § 387k(g)(1)(A). Second, it will "benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." *Id.* § 387k(g)(1)(B).

The Secretary of the Department delegated rulemaking authority to the FDA Commissioner. *See, e.g.*, FDA Staff Manual Guide § 1410.10 (Aug. 26, 2016); *id.* § 1410.10 (Nov. 17, 2015). The FDA Commissioner, in turn, redelegated rulemaking authority to the FDA Associate Commissioner for Policy. *See id.* § 1410.21(1)(G) (July 5, 2012). According to the 2012 FDA Staff Manual Guide, the Associate Commissioner for Policy had 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*.

In April 2014, the FDA published a proposed rule to deem e-cigarettes, among other items, "tobacco products" under the Act. *See* 79 Fed. Reg. 23,142, 23,143 (Apr. 25, 2014). The comment period was extended until August 8, 2014. *See id*. at 35,711 (June 24, 2014). After considering comments, FDA Associate Commissioner for Policy Leslie Kux promulgated a rule in May 2016 that deemed e-cigarettes to be "tobacco products" subject to the Act's requirements. *See* Deeming Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 28,974, 28,976 (May 10, 2016) (codified at 21 C.F.R. §§ 1100, 1140, 1143) ("Deeming Rule").

On January 30, 2018, appellants sued the FDA challenging the Deeming Rule under the Appointments Clause and the First Amendment of the Constitution. The district court, exercising its discretion to consider the Appointments Clause challenge even though it was not raised during the rulemaking, granted summary judgment to the FDA. Appellants appeal, and our review is *de novo*, *see Mayo v. Reynolds*, 875 F.3d 11, 19 (D.C. Cir. 2017).

II.

The Appointments Clause requires that "all . . . Officers of the United States" be appointed by the President "by and with the Advice and Consent of the Senate." U.S. CONST. art. II, § 2, cl. 2. "This requirement is the 'default manner of appointment,' *Edmond v. United States*, 520 U.S. 651, 660, 117 S. Ct. 1573, 137 L.Ed.2d 917 (1997), with the only exception being that Congress may vest the appointment of 'inferior Officers' in 'the President alone,' 'Courts of Law,' and 'the Heads of Departments,' U.S. CONST. art. II, § 2, cl. 2." *Guedes*

v. Bureau of Alcohol, Tobacco, Firearms & Explosives, 920 F.3d 1, 11 (D.C. Cir. 2019).

Appellants contend that the position of Associate Commissioner for Policy may be filled by only a properly appointed officer of the United States, and that Kux was not appointed as either an inferior or principal officer. They maintain that Kux's issuance of the Deeming Rule was consequently in violation of the Appointments Clause and void *ab initio*. *See* Appellants' Br. 49–60. The FDA rejects the challenge to Kux's authority and points further to ratifications of the Deeming Rule by FDA Commissioners Robert Califf and Scott Gottlieb. Either ratification, it maintains, suffices to render the Rule constitutional. *See* Appellees' Br. 16–27, 31–38.

"Ratification occurs when a principal sanctions the prior actions of its purported agent." *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 by statute on other grounds*, Federal Vacancies Reform Act of 1998, Pub. L. No. 105-277, 112 Stat. 2681 (1998) (codified at 5 U.S.C. §§ 3345 to 3349d), as this court recognized in *Guedes*, 920 F.3d at 13. This court 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. *Wilkes-Barre Hosp. Co., LLC v. NLRB*, 857 F.3d 364, 371 (D.C. Cir. 2017) (citing *Intercollegiate Broad. Sys., Inc. v. Copyright Royalty Bd.*, 796 F.3d 111, 117–21, 124 (D.C. Cir. 2015)). Even assuming for purposes of argument, as appellants object, that Kux's issuance of the Deeming Rule violated the Appointments Clause and that Commissioner Califf's general ratification of prior actions by the FDA as part of an agency

reorganization was invalid, Commissioner Gottlieb's ratification cured any Appointments Clause defect.

A.

On April 3, 2019, noting that the "authority under which the Deeming Rule was issued has been questioned in litigation," then-FDA Commissioner Scott Gottlieb stated: "To resolve these questions, 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." Ratification of the Deeming Rule, 81 Fed. Reg. 28,974 (May 10, 2016) (signed by Scott Gottlieb, M.D., on Apr. 3, 2019). He specified: "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.*

Appellants' challenges to the effectiveness of Commissioner Gottlieb's ratification fail. They maintain that Commissioner Gottlieb lacked the authority to ratify the Deeming Rule after they filed suit in federal district court. Even assuming this challenge is not forfeited by their failure to raise it in the district court, *see Salazar ex rel. Salazar v. District of Columbia*, 602 F.3d 431, 437 (D.C. Cir. 2010), appellants fail to distinguish *FEC v. Legi-Tech, Inc.*, 75 F.3d 704, 707–09 (D.C. Cir. 1996), where the court held that the Federal Election Commission effectively ratified its prior actions even though its ratification occurred after Legi-Tech alleged an Appointments Clause violation.

Appellants further maintain that "Commissioner Gottlieb lacked the power to issue the Deeming Rule in April 2019 because to do so would have been arbitrary and capricious."

Appellants' Br. 28. In appellants' view, for ratification to be effective, a ratifying party "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*." *Id*. (quoting *FEC v. NRA Political Victory Fund*, 513 U.S. 88, 98 (1994)). Relying on *Butte County v. Hogen*, 613 F.3d 190 (D.C. Cir. 2010), for the proposition that administrative officials must consider new evidence in order to make non-arbitrary, reasoned decisions, appellants note that during the nearly three years between the Deeming Rule's issuance and Commissioner Gottlieb's ratification, "dozens of public comments submitted to FDA had pointed the Commissioner to a wealth of new evidence regarding the benefits of vaping to public health." Appellants' Br. 30. *Butte County* does not advance appellants' position. In that case, the agency failed to consider a report that was submitted while the "issue was still pending before the Secretary." *Butte County*, 613 F.3d at 195. Here, the rulemaking record closed in 2016 and consequently Commissioner Gottlieb had no such obligation to consider new evidence in 2019. Therefore, it was not arbitrary and capricious for him to ratify the Deeming Rule without considering the new evidence that appellants reference.

Furthermore, nothing in the record indicates that Commissioner Gottlieb, when he ratified the Deeming Rule, failed "to conduct an independent evaluation of the merits," *Intercollegiate Broadcasting*, 796 F.3d at 117, or to make "a detached and considered judgment," *Doolin Sec.*, 139 F.3d at 213. Nor do appellants suggest that Commissioner Gottlieb was "actually biased." *Legi-Tech*, 75 F.3d at 709.

Because Commissioner Gottlieb effectively ratified the Deeming Rule, the court need not consider appellants' Appointments Clause objections to Commissioner Califf's ratification or to Associate Commissioner for Policy Kux's

issuance of the Rule. Given that the Act does not mandate administrative exhaustion as a prerequisite to judicial review, the court also need not address the FDA's alternative contention that appellants forfeited their Appointments Clause claim by failing to raise it before the agency. *See Darby v. Cisneros*, 509 U.S. 137, 147 (1993); 21 U.S.C. § 387*l* (2018).

B.

Notwithstanding Commissioner Gottlieb's effective ratification, appellants contend that Appointments Clause violations are *per se* harmful, not curable by ratification, and so the court should consider the merits of their challenge to the Deeming Rule and the asserted "continuing prejudice" they suffer. Appellants' Br. 41–46. They suggest that a different notice-and-comment process might "affect the contents or even the existence of a new Deeming Rule" in view of the "new evidence accumulated since the Deeming Rule's issuance" and the "FDA's post-promulgation guidances . . . [that] have effectively, though only informally, eased some of the original Deeming Rule's effects." *Id.* at 42–45. In *Legi-Tech*, 75 F.3d at 708–09, this court rejected the view that prejudice must be presumed for Appointments Clause violations. Subsequently, in *Intercollegiate Broadcasting*, 796 F.3d at 124, the court emphasized that "not every possible kind of taint is fatal" and that "speculative taint" such as the possibility that an invalid action was subsequently affirmed "simply out of agency solidarity" is insufficient.

Appellants demonstrate no "continuing prejudice." In the preamble to the Rule, the FDA acknowledged that there was uncertainty about the health effects of e-cigarettes, but concluded that the regulation of e-cigarettes "will still benefit public health" even if e-cigarettes "may eventually be shown to have a net benefit on or harm to public health at the

population level." Deeming Rule, 81 Fed. Reg. 28,974, 28,984 (May 10, 2016). Absent record evidence of continuing prejudice, the court will take Commissioner Gottlieb's ratification "at face value and treat it as an adequate remedy." *Wilkes-Barre Hosp.*, 857 F.3d at 372 (quoting *Legi-Tech*, 75 F.3d at 709).

Contrary to appellants' suggestion that ratification of an action "merely moots an Appointments Clause claim, and the voluntary cessation exception to mootness applies," Appellants' Br. 46, this court has "repeatedly held that a properly appointed official's ratification of an allegedly improper official's prior action, rather than mooting the claim, resolves the claim on the merits by 'remedy[ing] [the] defect' (if any) from the initial appointment." *Guedes*, 920 F.3d at 13 (quoting *Wilkes-Barre Hosp.*, 857 F.3d at 371). Commissioner Gottlieb's ratification, for the reasons discussed, cured any potential Appointments Clause defect arising from Associate Commissioner for Policy Kux's issuance of the Deeming Rule.

II.

Appellants further challenge the Act's preclearance pathway for modified risk tobacco products, which the Deeming Rule makes applicable to e-cigarettes, as violative of the First Amendment. This challenge is foreclosed by *Nicopure Labs, LLC*, 944 F.3d 267. There, the court found unpersuasive the objection that appellants make now, namely that the Deeming Rule 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 make them. *See id*. at 282–90; Appellants' Br. 60–64. The court sustained the preclearance pathway even when applied to modified-risk statements that manufacturers insist are "accurate" — such as claims that e-cigarettes contain less

of or are free of specified ingredients — because "modified risk claims that might be technically accurate if viewed in isolation are in fact often misunderstood by consumers." *Id*. at 287.

Accordingly, we affirm the grant of summary judgment to the FDA.