United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 7, 2021 Decided July 20, 2021

No. 20-5266

CIGAR ASSOCIATION OF AMERICA, ET AL.,
APPELLANTS

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:16-cv-01460)

Michael J. Edney argued the cause for appellants. With him on the briefs were *Shannen W. Coffin*, *Mark S. Raffman*, and *Andrew Kim*.

Lindsey Powell, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Brian M. Boynton*, Acting Assistant Attorney General, *Mark B. Stern* and *Alisa B. Klein*, Attorneys, and *Annamarie Kempic*, Deputy Chief Counsel for Litigation Food and Drug Division, Department of Health and Human Services.

Andrew N. Goldfarb and *William B. Schultz* were on the brief for *amici curiae* Public Health Groups in support of appellees.

Before: ROGERS, TATEL and WALKER, *Circuit Judges*.

Opinion for the Court by *Circuit Judge* ROGERS.

Concurring Opinion by *Circuit Judge* WALKER.

ROGERS, *Circuit Judge*: This is a continuing challenge by three non-profit trade associations to the Food and Drug Administration ("FDA") rule deeming cigars and pipe tobacco, among other tobacco products, to be subject to regulation under the Tobacco Control Act. Last year, this court held that the rule's warning requirements for cigars and pipe tobacco violated the Tobacco Control Act and the Administrative Procedure Act. *Cigar Ass'n of Am. v. FDA*, 964 F.3d 56, 61–64 (D.C. Cir. 2020). Now the trade associations challenge other unrelated aspects of the rule as well as an accompanying rule assessing user fees for manufacturers and importers of cigars and pipe tobacco but not of other newly deemed products like e-cigarettes. For the following reasons, we affirm the grant of summary judgment to FDA.

I.

The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) ("Tobacco Control Act"), amended the Federal Food, Drug, and Cosmetic Act "to establish a comprehensive regulatory scheme for tobacco products." *Cigar Ass'n of Am.*, 964 F.3d at 59. The Tobacco Control 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." 21 U.S.C. § 321(rr)(1). It regulates "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," as well as "any other tobacco products" that FDA "by regulation deems to be subject to" the Tobacco Control Act. *Id*. § 387a(b); *Office of the Commissioner Reorganization*, 74 Fed. Reg. 41,713, 41,732 (Aug. 18, 2009).

In May 2016, FDA promulgated a rule deeming all products that meet the Tobacco Control Act's definition of "tobacco product," including any "component" and "part" but excluding any "accessory" of those products, to be subject to the Tobacco Control Act. *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,974, 28,975 (May 10, 2016) (codified at 21 C.F.R. §§ 1100, 1140 & 1143) ("Deeming Rule"). Noting that it was "using the terms 'component' and 'part' interchangeably and without emphasizing the distinction between the terms," FDA defined "component or part" to mean "any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents or characteristics; or (2) to be used with or for the human consumption of a tobacco product." *Id*. In the preamble, it stated that a pipe used to consume pipe tobacco was such a "component or part." *Id*. at 29,042.

"The Deeming Rule subjects newly regulated tobacco products, including cigars and pipe tobacco, to requirements akin to those previously imposed by statute on cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." *Cigar Ass'n of Am.*, 964 F.3d at 60. One such

requirement is premarket review by FDA before the introduction into interstate commerce of any "new tobacco product," defined as a tobacco product that "was not commercially marketed in the United States as of February 15, 2007" or that was modified after that date. 21 U.S.C. §§ 387j(a)(1)–(2). This lookback date is called the "grandfather date." Under the Tobacco Control Act, manufacturers may obtain premarket authorization by showing that "the tobacco product is substantially equivalent . . . to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that [FDA] has previously determined . . . is substantially equivalent." *Id.* § 387e(j)(1)(A)(i). To do so, they must submit a "report to [FDA] (in such form and manner as [FDA] shall prescribe)." *Id.* § 387e(j)(1).

To allow manufacturers time to prepare premarket review applications, in the preamble to the Deeming Rule, FDA adopted "staggered compliance periods" during which it would defer enforcement of the Tobacco Control Act's premarket review requirements for newly deemed products that were being marketed as of the Rule's effective date. 81 Fed. Reg. at 29,010. Pertinently, it stated that it did not intend to enforce the requirements for 18 months from the Rule's effective date while manufacturers submitted substantial equivalence reports and for an additional 12 months while it reviewed those reports. *See id.* at 29,011.

On the same day that it issued the Deeming Rule, FDA promulgated a separate rule addressing the assessment of user fees for manufacturers and importers of cigars and pipe tobacco. *See Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco*, 81 Fed. Reg. 28,707 (May 10, 2016) (codified at 21 C.F.R. § 1150) ("User Fees

Rule"). In the preamble, FDA stated that it was precluded by the Tobacco Control Act from assessing user fees for manufacturers and importers of tobacco products, such as e-cigarettes, beyond six enumerated classes of tobacco products. *See id*. at 28,709–11.

Appellants, three non-profit trade associations representing cigar and pipe tobacco manufacturers, importers, distributors, suppliers, and consumers, filed a lawsuit challenging the Deeming Rule and the User Fees Rule in the district court in July 2016. FDA announced in July 2017 that it intended to make regulatory changes that might affect certain of appellants' claims. *See Cigar Ass'n of Am. v. FDA*, 315 F. Supp. 3d 143, 158 (D.D.C. 2018). Appellants have since "sought resolution of their claims piecemeal." *Cigar Ass'n of Am. v. FDA*, 480 F. Supp. 3d 256, 265 (D.D.C. 2020). The present appeal concerns only the district court's grant of summary judgment to FDA on five of appellants' Administrative Procedure Act ("APA") challenges to the Deeming Rule concerning its implementation of the Tobacco Control Act's premarket review requirements, underlying cost-benefit analysis, and classification of a pipe as a "component or part" of a tobacco product subject to regulation under the Tobacco Control Act, as well as appellants' APA challenge to the User Fees Rule. *See Cigar Ass'n of Am. v. FDA*, 480 F. Supp. 3d at 266–77; *Cigar Ass'n of Am.*, 315 F. Supp. 3d at 177–82, 185–88.

II.

The court must uphold agency action under the APA unless it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2). Further, the "court is not to substitute its judgment for that of the agency, but instead to assess only whether the decision was

based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1905 (2020) (internal citations and quotation marks omitted). When the district court reviews agency action under the APA, the court reviews the district court's decision *de novo*. *Cigar Ass'n of Am.*, 964 F.3d at 61. Applying that standard, appellants' APA challenges to the Deeming Rule and the User Fees Rule in the instant case are unpersuasive.

A. The Deeming Rule

1. Appellants first challenge FDA's failure to provide instructions about the form and manner of substantial equivalence reports specific to cigars and pipe tobacco. They emphasize that the Tobacco Control Act provides that manufacturers shall "at least 90 days prior to making such introduction or delivery, report to the Secretary (*in such form and manner as the Secretary shall prescribe*)." 21 U.S.C. § 387e(j)(1) (emphasis added).

The court need not decide whether § 387e(j)(1) required FDA to supply product-specific instructions before the due date for substantial equivalence reports. In the preamble to the Deeming Rule, FDA stated that it did not intend to enforce the Act's premarket review requirements for 18 months from the Rule's effective date while manufacturers submitted substantial equivalence reports. *See* 81 Fed. Reg. at 29,011. Appellants acknowledge that FDA did not need to include any form and manner instructions in the Deeming Rule itself and could have provided such instructions after the Rule's promulgation. *See* Appellants Br. 18–19; Oral Arg. Rec. 2:02. Therefore, even assuming FDA's failure to provide such instructions violated § 387e(j)(1), that failure is not an error stemming from the Deeming Rule.

Furthermore, the court need not consider appellants' contention that FDA acted arbitrarily and capriciously by inadequately considering "whether instructions needed to be in place before substantial equivalence reports were due," Appellants Br. 20–21, because appellants "forfeited" it by failing to raise it before the district court, *Cigar Ass'n of Am.*, 480 F. Supp. 3d at 274; *see District of Columbia v. Air Florida, Inc.*, 750 F.2d 1077, 1084 (D.C. Cir. 1984).

2. Appellants next contend that the Deeming Rule is arbitrary and capricious because FDA premised the Rule's effective date and due date for substantial equivalence reports on the faulty assumption that it "could set an initial due date for substantial equivalence reports and defer evaluation of the instructions provided for those reports, as it could always adjust the due date later." Appellants Br. 28. They highlight that in the preamble to the Deeming Rule, FDA repeatedly stated that "[a]gency compliance/enforcement policies are not subject to the requirements that govern notice-and-comment rulemaking." *Id.* at 27 (quoting 81 Fed. Reg. at 28,977, 29,010). Yet appellants note that, contrary to FDA's statements, the district court for the District of Maryland held in litigation relating to the Deeming Rule that "any change in the due date had to go through notice-and-comment rulemaking" and that "FDA's selection of an effective date *anchored* whatever discretion FDA might have to set a later due date for substantial equivalence reports." *Id.* at 28–29 (citing *Am. Academy of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 470, 492 (D. Md. 2019)).

This contention fails on its own terms. Even assuming FDA misconceived the law, appellants fail to show that FDA set the Rule's effective date and due date for substantial equivalence reports "based on" those misconceptions. *Phillips Petroleum Co. v. FERC*, 792 F.2d 1165, 1171 (D.C. Cir. 1986).

They point to nothing in the Deeming Rule itself or the rulemaking record showing that those misconceptions "drove the FDA's approach to addressing its obligations under [§ 387e(j)(1)] and whether it had provided adequate instructions for cigar and pipe tobacco substantial equivalence reports." Appellants Br. 28.

3. Also meritless is appellants' contention that FDA arbitrarily concluded that it lacked authority under the Tobacco Control Act to alter the statutory grandfather date for cigars and pipe tobacco. *See id.* at 31–40. None of the provisions identified by appellants grant FDA authority to alter that date. Section 387a(b), which authorizes FDA to "deem" tobacco products to be subject to the Tobacco Control Act's requirements, does not give FDA authority to modify those requirements. *See Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 281 (D.C. Cir. 2019). Even assuming § 387f(a) is an authorizing provision, it plainly does not authorize revisions to § 387j(a), which sets the grandfather date for substantial equivalence reports. Likewise, § 387e(j)(3) is inapposite because it authorizes FDA to exempt from premarket review requirements only "tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive." And neither § 387f(d) nor § 387g(a)(3)(A) authorizes FDA to design a regulatory scheme for cigars and pipe tobacco excluding the substantial equivalence process and its grandfather date. *See* Appellants Br. 37–38. Those provisions authorize FDA to issue regulations about "restrictions on the sale and distribution of a tobacco product" and "tobacco product standards . . . appropriate for the protection of the public health" respectively. 21 U.S.C. §§ 387f(d)(1), 387g(a)(3)(A). They do not grant FDA authority to eliminate any of the Tobacco Control Act's premarket review requirements, including the grandfather date.

4. Further, there is no merit to appellants' contention that FDA's cost-benefit analysis in its Final Regulatory Impact Analysis was arbitrary or capricious. *See* FDA, *Final Regulatory Impact Analysis, Final Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis*, Docket No. FDA-2014-N-0189 (May 10, 2016) ("Reg. Impact"). Notwithstanding the absence of a statutory duty, "when an agency decides to rely on a cost-benefit analysis as part of its rulemaking," that analysis may be reviewable under the APA. *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012). Nevertheless, because the court reviews cost-benefit analyses "deferentially," appellants' "burden to show error is high." *Id*. (internal citations omitted).

The court need not decide the non-jurisdictional issue of whether FDA's cost-benefit analysis was reviewable. *See Friends of Animals v. Bernhardt*, 961 F.3d 1197, 1207 (D.C. Cir. 2020). Assuming the analysis was reviewable, appellants fail to meet their burden. Appellants' principal contention is that FDA failed to analyze the specific costs and benefits of subjecting cigars and pipe tobacco to the Tobacco Control Act's premarket review requirements. *See* Appellants Br. 41–42. According to appellants, in contrast to its detailed analysis of the benefits of subjecting e-cigarettes to premarket review, FDA "never even tried to describe in any detail, much less put a number on, the benefits of premarket review for cigars and pipe tobacco." *Id.* at 42. But appellants cite no authority for the proposition that FDA needed to consider the benefits of premarket review specifically for each industry or product affected by the Deeming Rule. Nor, contrary to appellants' suggestion, does the purpose of the Deeming Rule compel that FDA's cost-benefit analysis take a particular form. *See id*. Further, although appellants do not dispute that FDA separately quantified the costs of subjecting cigars and pipe tobacco to

substantial equivalence review, *see, e.g.*, Reg. Impact at 95–96, they complain in passing about "FDA's arbitrary treatment of the costs of the [premarket review] process," Appellants Br. 43. Their conclusory objections to FDA's approach to calculating costs do not overcome our deferential review of such agency calculations. *See Nat'l Ass'n of Home Builders*, 682 F.3d at 1040.

5. Challenging a different aspect of the Deeming Rule, appellants object to FDA's classification of a pipe as a "component or part" of a tobacco product subject to the Tobacco Control Act, rather than an "accessory" not subject to the Act. To determine whether FDA's interpretation accords with the Tobacco Control Act, the court applies the familiar *Chevron* two-step framework. *See Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 636 (D.C. Cir. 2021). At *Chevron* step one, "employing traditional tools of statutory construction," the court considers "whether Congress has directly spoken to the precise question at issue." *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842, 843 n.9 (1984). "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842–43. If the statute is ambiguous, then, at *Chevron* step two, "the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id*. at 843.

Therefore, the court "begin[s] with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 252 (2004) (internal citation omitted). The Tobacco Control 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." 21 U.S.C. § 321(rr)(1). Appellants do not dispute that by leaving the term "component, part, or accessory" undefined, Congress "explicitly left a gap for the agency to fill." *Chevron*, 467 U.S. at 843. Instead, they maintain that the Deeming Rule's definition of the term "component or part" contradicts § 321(rr)(1)'s definition of the term "tobacco product."

In appellants' view, a "'component' must be '*of* a tobacco product' in the sense of being integrated into such a product." Appellants Br. 45. Because a pipe "exist[s] separate from the tobacco product being consumed" and is not "integrated into a single product," appellants maintain that a pipe cannot be a "component." *Id*. The Tobacco Control Act's text does not, however, unambiguously support appellants' interpretation. Neither § 321(rr)(1)'s phrase "of a tobacco product" nor dictionary definitions of "component" compel appellants' interpretation that a "component" must be integrated into a tobacco product. *See* Appellants Br. 44–45. Nor, as appellants' suggest, does § 321(rr)(1) "command that *all* tobacco products, including components, be 'made or derived from tobacco.'" *Id.* at 45 (quoting 21 U.S.C. § 321(rr)(1)). To interpret § 321(rr)(1) as imposing such a limitation would render superfluous the phrase "including any component, part, or accessory of a tobacco product." *See Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 386 (2013). That the Tobacco Control Act elsewhere uses the term "component parts" to include the "filter" or "paper" of a cigarette further indicates that a "component or part" need not itself be made or derived from tobacco. 21 U.S.C. § 387g(a)(1)(A). Because the Tobacco Control Act does not unambiguously foreclose FDA's interpretation of the term "component or part," the court proceeds to *Chevron* step two. *See Catawba Cty. v. EPA*, 571 F.3d 20, 35 (D.C. Cir. 2009).

At *Chevron* step two, the court defers to the agency's permissible interpretation "only if the agency has offered a reasoned explanation for why it chose that interpretation." *Vill. of Barrington, Ill. v. Surface Transp. Bd.*, 636 F.3d 650, 660 (D.C. Cir. 2011). "The analysis of disputed agency action under *Chevron* Step Two and arbitrary and capricious review is often 'the same, because under *Chevron* step two, [the court asks] whether an agency interpretation is arbitrary or capricious in substance.'" *Agape Church, Inc. v. FCC*, 738 F.3d 397, 410 (D.C. Cir. 2013) (quoting *Judulang v. Holder*, 565 U.S. 42, 52 n.7 (2011)).

Appellants do not contest that a pipe meets the Deeming Rule's definition of "component or part." Nor do they offer any additional arguments at *Chevron* step two as to why that definition is impermissible under the Tobacco Control Act or lacks a reasonable explanation by FDA. Rather, appellants contend that FDA arbitrarily and capriciously failed to explain how "pipes themselves have any direct effect on public health" and how "a mere container would meaningfully affect any health consequences associated with the tobacco placed in it." Appellants Br. 46. This contention is unavailing. The Deeming Rule's definition of "component or part" does not require FDA to identify a product's health effects in order to classify it as a "component or part," *see* 81 Fed. Reg. at 28,975, and appellants cite no authority for imposing that requirement. Therefore, FDA's classification of a pipe as a "component or part" is not arbitrary or capricious and survives *Chevron* step two.

B. The User Fees Rule

Appellants contend that FDA arbitrarily assessed user fees for manufacturers and importers of cigars and pipe tobacco but not of other newly deemed tobacco products like e-cigarettes.

See Appellants Br. 47–53. They maintain that FDA incorrectly concluded that the Tobacco Control Act precluded it from imposing user fees on e-cigarettes. *See id.* at 47. As before, the court reviews FDA's interpretation under the *Chevron* two-step framework. *See Chevron*, 467 U.S. at 842–43.

Here, the Tobacco Control Act provides that FDA "shall *in accordance with this section* assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products subject to this subchapter." 21 U.S.C. § 387s(a) (emphasis added). It sets the "total amount of user fees authorized to be assessed and collected" for each fiscal year. *Id.* § 387s(b)(1). It then provides a two-stage process by which FDA is to determine the assessment of user fees. At the first stage, the total user fees to be assessed with respect to each class of tobacco products is the total amount of user fees for that fiscal year multiplied by the "applicable percentage" for each class for the fiscal year. *Id.* § 387s(b)(2)(A). The "applicable percentage" for six enumerated classes of tobacco products — cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco — is the percentage set pursuant to 7 U.S.C. § 518d(c) of the Fair and Equitable Tobacco Reform Act ("FETRA"). *Id.* §§ 387s(b)(2)(B)(i)–(ii). FETRA lists initial percentages for each of the six enumerated classes of tobacco products, totaling 100 percent, and describes how percentages for those six classes should be adjusted for subsequent fiscal years to reflect changes in shares of gross domestic volume. 7 U.S.C. §§ 518d(c)(1)–(2). At the second stage, the "percentage share" of each manufacturer and importer within a particular class of tobacco products is the percentage set in §§ 518d(e)–(h) of FETRA. 21 U.S.C. §§ 387s(b)(3)–(4).

Notwithstanding Congress' detailed user fee scheme, appellants maintain that nothing in the Tobacco Control Act's

text precludes the assessment of user fees on non-enumerated classes of tobacco products, like e-cigarettes. *See* Appellants Br. 48. In their view, by addressing the assessment of user fees for only six enumerated classes of tobacco products, Congress left a gap for FDA to determine how to assess user fees for non-enumerated classes of tobacco products. *See id*. at 49–50. Yet by mandating that FDA look to FETRA to determine the "applicable percentage" of user fees for the six enumerated classes of tobacco products and the "percentage share" of each manufacturer and importer within those classes, Congress has limited the assessment of user fees to manufacturers and importers of the six enumerated classes of tobacco products. Thus, "Congress has directly spoken to the precise question" of against which classes of tobacco products FDA can assess user fees. *Chevron*, 467 U.S. at 842. Appellants offer no satisfactory explanation as to how FDA could, consistent with the Tobacco Control Act and the cross-referenced FETRA provisions, define an applicable percentage for a non-enumerated class of tobacco products when Congress has allocated 100 percent of the total user fees to six enumerated classes of tobacco products. Adding an applicable percentage for a non-enumerated class would increase the total to over 100 percent and require FDA to assess user fees beyond the total amount for the fiscal year set in § 387s(b)(1). *See* 81 Fed. Reg. at 28,709. Even assuming FDA could define an applicable percentage for a non-enumerated class of tobacco products, appellants do not dispute that the information needed for calculating the "percentage share" of each manufacturer and importer under FETRA is unavailable for non-enumerated classes of tobacco products like e-cigarettes. *See id*. at 28,710–12.

To the extent appellants contend that the Tobacco Control Act's text is ambiguous because it directs FDA to assess user fees on "*each* manufacturer and importer *of tobacco products*

subject to this subchapter," including e-cigarettes, they appear to ignore the statutory limitation imposed by Congress. Appellants Br. 48 (quoting 21 U.S.C. § 387s(a) and adding emphasis). Section 387s(a) provides that FDA's user-fees assessment authority on "each manufacturer and importer of tobacco products subject to this subchapter" "shall [be] *in accordance with this section*." (emphasis added). As described, "this section" limits the assessment of fees to six enumerated classes. In view of the limiting phrase "in accordance with this section," § 387s(a) introduces no ambiguity at *Chevron* step one.

Nor does appellants' invocation of the structure and purpose of the statutory scheme. User fees "are the only funds authorized to be made available for tobacco regulation activities." 21 U.S.C. § 387s(c)(2)(B)(i). Appellants assert that as the market for e-cigarettes grows, "e-cigarettes threaten to swamp the agency's tobacco regulation budget and to compel the manufacturers of six classes of tobacco products to spend hundreds of millions to regulate an entirely different product." Appellants Br. 51. But appellants proffer no evidence in support of their bald assertion, much less a basis for connecting the increased e-cigarette use among high school students and the anticipated number of e-cigarette premarket review applications to FDA. *See id.* (citing 81 Fed. Reg. at 28,984 and Reg. Impact at 84). Even when ambiguity may be found by reference to the "broader context of the statute as a whole," *United States v. Wilson*, 290 F.3d 347, 353 (D.C. Cir. 2002) (internal citation omitted), "there must be evidence that Congress meant something other than what it literally said before a court can depart from plain meaning," *Eagle Pharms., Inc. v. Azar*, 952 F.3d 323, 332–33 (D.C. Cir. 2020) (quoting *Engine Mfrs. Ass'n v. EPA*, 88 F.3d 1075, 1088 (D.C. Cir. 1996)). Appellants cannot dispute that Congress chose to rely on FETRA's methodology to determine the assessment of user

fees under the Tobacco Control Act and that FETRA's methodology cannot be used for non-enumerated classes of tobacco products like e-cigarettes. Their invocation of the general purpose of user fees is unsupported by evidence that would allow FDA to depart from Congress' specific scheme for determining the assessment of user fees.

Even if the Tobacco Control Act were ambiguous about whether FDA may impose user fees on non-enumerated classes of tobacco products, FDA reasonably explained, in the alternative, that it "would adopt the same interpretation of the statute in an exercise of its discretion." 81 Fed. Reg. at 28,711. Agencies may "employ bright-line rules for reasons of administrative convenience, so long as those rules . . . are reasonably explained." *Emily's List v. FEC*, 581 F.3d 1, 22 n.20 (D.C. Cir. 2009). Here, FDA explained why imposing user fees on non-enumerated classes of tobacco products would require "fashion[ing] an entirely novel framework for determining class percentage allocations and allocations within each class of tobacco product." 81 Fed. Reg. at 28,712. This explanation survives our "highly deferential" review at *Chevron* step two. *Vill. of Barrington, Ill.*, 636 F.3d at 667.

Accordingly, we affirm the grant of summary judgment to FDA on appellants' current challenges to the Deeming Rule and the User Fees Rule.

WALKER, *Circuit Judge*, concurring: I agree with the Court that the Food and Drug Administration had the statutory authority to classify a smoking pipe as a "component" or "part" of a tobacco product. 21 U.S.C. § 321(rr)(1). Without a pipe, pipe tobacco cannot be smoked in the manner its ordinary purchaser expects when he buys it. In addition, nothing in the text requires a component or part to be, as the Plaintiffs argue, fully "integrated into a single product." Appellants' Br. 45. Finally, although a pipe is not made from tobacco, neither are a cigarette's filter and paper, which are "component parts" of a tobacco product under the express terms of the Tobacco Control Act. 21 U.S.C. § 387g(a)(1)(A). Because in my view "the intent of Congress is clear," I would not proceed on that question past *Chevron* step one. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-43 (1984) ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."); *cf. Natural Resources Defense Council v. EPA*, 489 F.3d 1364, 1373 (D.C. Cir. 2007) ("the absence of a statutory definition does not render a word ambiguous"). Except as to that point, I join the Court's opinion in full.