United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 29, 2019 Decided July 7, 2020

No. 18-5195

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 *Mark S. Raffman* and *Andrew Kim*.

Mark Brnovich, Attorney General, Office of the Attorney General for the State of Arizona, and *Keith Miller*, Senior Litigation Counsel, were on the brief for *amicus curiae* State of Arizona in support of appellants.

Lindsey Powell, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Jessie K. Liu*, U.S. Attorney, *Mark B. Stern*, *Alisa B. Klein*, and *Tyce R. Walters*, Attorneys, U.S. Department of Justice, and *Robert P. Charrow*, General Counsel, U.S. Department of Health and Human Services.

Nandan M. Joshi, *Allison M. Zieve*, and *Scott L. Nelson* were on the brief for *amicus curiae* Public Citizen in support of appellees.

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

Rachel Bloomekatz was on the brief for *amicus curiae* Public Health Law Center in support of appellees.

Justin M. Pearson and *Paul M. Sherman* were on the brief for *amicus curiae* J. Scott Armstrong in support of neither party.

Before: GARLAND and KATSAS, *Circuit Judges*, and RANDOLPH, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* KATSAS.

KATSAS, *Circuit Judge*: The Tobacco Control Act permits the Food and Drug Administration to regulate tobacco products for the public health, but only after considering whether the regulation would likely increase or decrease the number of smokers. Under this authority, the FDA promulgated regulations requiring extensive health warnings on packaging and in advertising for cigars and pipe tobacco. The FDA concluded that these warnings would help communicate the health risks of smoking, but it failed to consider how the warnings would likely affect the number of smokers. We hold that this failure violated the Tobacco Control Act and the Administrative Procedure Act.

I

A

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 (FDCA) to establish a comprehensive regulatory scheme for tobacco products. As amended, the FDCA regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. 21 U.S.C. § 387a(b). The FDCA also now extends to "any other tobacco products" that the Secretary of Health and Human Services "by regulation deems to be subject to" the FDCA. *Id.* The FDCA further provides that the Secretary may by regulation restrict the sale or distribution of any tobacco product if he "determines that such regulation would be appropriate for the protection of the public health." *Id.* § 387f(d)(1). In making that determination, the Secretary must consider the likelihood that the regulation will increase or decrease the number of tobacco users in the overall population. *See id.* The FDA administers the Tobacco Control Act for the Secretary. *See id.* § 387a(e); Office of the Commissioner Reorganization, 74 Fed. Reg. 41,713, 41,732 (Aug. 18, 2009).

Under this authority, the FDA promulgated a regulation deeming the FDCA to cover all tobacco products. Deeming Tobacco Products to Be Subject to the FDCA, 81 Fed. Reg. 28,973 (May 10, 2016) (Deeming Rule). 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. *Id.* at 28,976. To that end, it requires extensive health warnings on packages and in advertisements for cigars and pipe tobacco.

The Deeming Rule makes it unlawful to manufacture or sell any cigar product without one of six rotating warning statements. 21 C.F.R. § 1143.5(a)(1). Collectively, the warnings inform prospective and current smokers that cigars cause various diseases, create pregnancy risks, are addictive, and are not a safe alternative to cigarettes. *Id.* The warnings must be printed on at least thirty percent of the two "principal display panels" of each cigar package, with contrasting white-on-black or black-on-white ink. *See id.* § 1143.5(a)(2). For cigars sold individually, the warnings must appear on an 8.5 x 11-inch sign posted within three inches of the cash register. *Id.* § 1143.5(a)(3). For both kinds of warnings, the regulation specifies the necessary font, font size, capitalization, punctuation, and centering. *Id.* § 1143.5(a)(2)(ii)–(v), (a)(3)(ii)–(iv). The same warnings also must cover at least twenty percent of cigar advertisements. *Id.* § 1143.5(b). Manufacturers must submit to the FDA a "proposed warning plan" at least twelve months before selling or advertising any cigar product. *Id*. § 1143.5(c).

For pipe tobacco, packages and advertisements must bear a warning that the product contains nicotine, an addictive chemical. 21 C.F.R. § 1143.3(a)(1). The warning must follow the same formatting requirements as the warnings for cigars. *Id.* § 1143.3(a) (packaging); § 1143.3(b) (advertising).

In promulgating these requirements, the FDA stated that "[t]he warning statements required by this final rule will help consumers better understand and appreciate the risks and characteristics of tobacco products." Deeming Rule, 81 Fed. Reg. at 28,981. At the same time, the FDA acknowledged that "[r]eliable evidence on the impacts of warning labels … on users of cigars, pipe tobacco, waterpipe tobacco, and [electronic nicotine delivery systems] does not, to our knowledge, exist." Deeming Tobacco Products to Be Subject

to the FDCA, Final Regulatory Impact Analysis, ECF Doc. 81-2 at 62 (May 2016).

B

Three cigar and pipe tobacco industry associations challenged various provisions of the Deeming Rule in the district court. As relevant here, the plaintiffs argued that the warning requirements for cigars and pipe tobacco violate the Tobacco Control Act and the Administrative Procedure Act because the FDA did not adequately consider how the warnings would affect smoking. The plaintiffs also argued that the warning requirements violate the First Amendment.

The district court rejected these challenges to the warning requirements. On these claims, the court denied the plaintiffs' motion for summary judgment, granted the FDA's cross-motion for summary judgment, and denied as moot the plaintiffs' motion for a preliminary injunction. *Cigar Ass'n of Am. v. FDA*, 315 F. Supp. 3d 143, 159–74 (D.D.C. 2018). The court then entered final judgment on the claims under Federal Rule of Civil Procedure 54(b). J.A. 330. Finally, the court stayed enforcement of the warning requirements during this appeal. *Cigar Ass'n of Am. v. FDA*, 317 F. Supp. 3d 555 (D.D.C. 2018).

II

Our analysis begins, and ends, with the plaintiffs' statutory claims. Those claims arise under the Administrative Procedure Act, which provides for judicial review of any "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. The APA instructs a reviewing court to set aside agency action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A). When a district court reviews agency action

under the APA, we in turn review the district court's decision de novo. *See Deppenbrook v. PBGC*, 778 F.3d 166, 171–72 (D.C. Cir. 2015).

A

The plaintiffs contend that the cigar and pipe tobacco warning requirements are arbitrary and capricious because the agency failed to comply with the Tobacco Control Act. Under the APA, agency action is arbitrary and capricious if the agency "failed to consider an important aspect of the problem" before it, *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983), including any "factor the agency must consider under its organic statute," *Lindeen v. SEC*, 825 F.3d 646, 657 (D.C. Cir. 2016) (quotation marks omitted). When Congress requires an agency to consider something, we ask whether the agency has reached an "express and considered conclusion" pursuant to the statutory mandate. *Time Warner Entm't Co. v. FCC*, 56 F.3d 151, 175 (D.C. Cir. 1995) (quotation marks omitted). "Merely referencing a requirement is not the same as complying with that requirement. And stating that a factor was considered—or found—is not a substitute for considering or finding it." *Gerber v. Norton*, 294 F.3d 173, 185 (D.C. Cir. 2002) (cleaned up); *accord Susquehanna Int'l Grp., LLP v. SEC*, 866 F.3d 442, 446 (D.C. Cir. 2017) (same).

The FDA promulgated the warning requirements under section 906(d)(1) of the FDCA, which provides:

> The Secretary may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health.

> The Secretary may by regulation impose restrictions on the advertising and promotion of a tobacco product consistent with and to [the] full extent permitted by the first amendment to the Constitution. The finding as to whether such regulation would be appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—
>
> (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and
>
> (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

21 U.S.C. § 387f(d)(1).

Section 906(d)(1) establishes three clear propositions. First, the FDA "may" impose warning requirements for a tobacco product if it determines that the warnings are "appropriate for the protection of the public health." Second, this "finding" on public health "shall be determined" for the "population as a whole, including users and nonusers of the tobacco product." Third, the finding "shall … tak[e] into account" two further considerations: (A) the "likelihood that existing users of tobacco products will stop using such products" and (B) the "likelihood that those who do not use tobacco products will start using such products." Therefore, although the FDA "may" decide whether to regulate, it "shall" consider the two factors when doing so. And "[w]hen a statute distinguishes between 'may' and 'shall,' it is generally clear that 'shall' imposes a mandatory duty." *Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1977 (2016). The FDA

thus cannot regulate under section 906(d)(1) without considering the likely impact on tobacco cessation and adoption rates.

Our textual analysis fits comfortably with the rest of the Tobacco Control Act, which expresses a consistent concern for reducing smoking. In the Act, Congress found that "[b]ecause the only known safe alternative to smoking is cessation, interventions should target all smokers to help them quit completely." Tobacco Control Act § 2(34), 123 Stat. at 1779. Likewise, Congress specified a purpose "to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases." *Id.* § 3(9), 123 Stat. at 1782. As part of that goal, it invoked the FDA's expertise "to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm." *Id.* § 2(44), 123 Stat. at 1780. In section 906(d)(1), it specifically directed the FDA to consider the impact of any regulation on cessation and adoption rates—separately identified in their own subsections—even as the FDA considers other public-health issues as well. 21 U.S.C. § 387f(d)(1). And it required the FDA to assess cessation and adoption rates in justifying various other administrative actions concerning tobacco. *See id.* §§ 387g(a)(3)(B)(i) (product standards), 387j(c)(4) (new product approval).

Furthermore, our interpretation accords with common sense. The required package warnings occupy more than four times the surface area than do the package warnings previously required under settlements among large cigar manufacturers and the Federal Trade Commission. *See, e.g.*, *In re Swedish Match N. Am., Inc.*, Dkt. No. C-3970, 2000 WL 1207446 (F.T.C. Aug. 25, 2000). By the FDA's own estimate, the warnings will cost over $100 million to implement. Final Regulatory Impact Analysis, ECF Doc. 81-2 at 114–15. And

they affect the speech interests of manufacturers. *See*, *e.g.*, *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1211–12 (D.C. Cir. 2012). When requiring a product to bear such obtrusive and expensive health warnings, it is difficult to imagine a more important "aspect of the problem," *State Farm*, 463 U.S. at 43, than whether the warnings will actually affect product usage.

The FDA responds that section 906(d)(1) "does not require a finding that a regulation will reduce the use of tobacco products" and that Congress gave it "leeway to determine what measures would be appropriate for the protection of the public health, as long as the agency considered the effects of regulation across all populations." Appellees' Br. 23. The FDA is partially correct; section 906(d)(1) requires a "finding" only on whether the regulation under consideration "would be appropriate for the protection of the public health." But the provision then specifies how that finding "shall be determined," namely by addressing risks and benefits for the entire population "and taking into account" the two specific considerations that we have highlighted. We decline to read the latter requirement out of the statute.

B

The Deeming Rule does not consider the impact of health warnings on smoking cessation and adoption rates. In fact, the rule scrupulously avoids that issue, and the FDA barely even contends otherwise. Instead, the FDA candidly acknowledged that "[r]eliable evidence on the impacts of warning labels … on users of cigars [and] pipe tobacco … does not, to our knowledge, exist." Final Regulatory Impact Analysis, ECF Doc. 81-2 at 62.

The FDA now highlights its conclusion that the expanded health warnings are "an effective means to help consumers understand and appreciate the risks of using tobacco products."

Deeming Rule, 81 Fed. Reg. at 29,064; *see also id.* at 28,981. Perhaps the new warnings will more effectively convey health risks, but section 906(d)(1) also requires the FDA to consider "the increased or decreased likelihood" that consumers will act on that information by deciding not to smoke. Presumably the two issues are related, for consumers are unlikely to heed warnings that they do not read or cannot understand. But "the relatedness of the concept discussed to the statutorily mandated factor that the agency does not discuss does not relieve the agency of the duty of compliance with the congressional instruction." *Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1217 (D.C. Cir. 2004). Because the regulation contains no discussion tying the warnings to reduced smoking, the FDA failed to bridge the gap between effective communication and fewer smokers.

By its terms, section 906(d)(1) required the FDA to "tak[e] into account" whether the warning requirements would affect the number of smokers. Because the FDA declined even to consider that question, it violated section 906(d)(1) and acted arbitrarily and capriciously.

C

The district court held that the FDA satisfied section 906(d)(1) by making this statement in the notice of proposed rulemaking:

> Based on the available data on the addictiveness of nicotine ... , the known adverse health effects of some of the products covered by this proposed rule, such as certain cigars and waterpipes, the likelihood that users of these products could co-use or migrate to other tobacco products like cigarettes, and the risk that failure to act will reinforce consumers' existing confusion and misinformation about these products'

> safety or lack of harmfulness, FDA believes that the sale and distribution restrictions the Agency is proposing—minimum age and identification requirements (including vending machine requirements) and health warning requirements—meet the public health standard set forth in section 906(d) .... Specifically, FDA has concluded that the restrictions would be appropriate for the protection of the public health with respect to the risks and benefits to the population as a whole, including the increased likelihood that existing users will quit using tobacco products and the decreased likelihood that new users will initiate tobacco product use.

Deeming Tobacco Products to Be Subject to the FDCA, 79 Fed. Reg. 23,142, 23,146 (proposed Apr. 25, 2014) (NPRM); *see Cigar Ass'n*, 315 F. Supp. 3d. at 159–61.

We cannot uphold a final rule based on reasoning that appears only in the notice. The APA "prescribes a three-step procedure for so-called 'notice-and-comment rulemaking.'" *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 (2015). First, the agency must issue a "notice of proposed rulemaking." 5 U.S.C. § 553(b). Second, the agency must accept public comments. *Id.* § 553(c). Third, the agency must issue a final rule including a "general statement of … basis and purpose," *id.*, which must address significant comments and forms the basis for judicial review, *see Nat'l Mining Ass'n v. MSHA*, 512 F.3d 696, 700 (D.C. Cir. 2008); 1 K. Hickman & R. Pierce, *Administrative Law Treatise* § 5.4 (6th ed. 2019); 2 *id.* § 11.1. Not surprisingly, the statement of basis and purpose must come "after" consideration of comments and thus also "after notice required by" section 553(b). *See* 5 U.S.C. § 553(c). We thus cannot uphold a final rule based on strands of reasoning that precede public comment and appear nowhere in the final rule.

The district court reasoned that the Deeming Rule incorporated the notice. *See Cigar Ass'n*, 315 F. Supp. 3d. at 161 (citing Deeming Rule, 81 Fed. Reg. at 29,062). Here is the putative incorporation: "FDA finds there is a strong scientific basis to require health warnings on cigar packages and in cigar advertising (as well as on signs for unpackaged cigars), which was extensively discussed in the NPRM (79 Fed. Reg. 23,142, at 23,167 through 23,170)." Deeming Rule, 81 Fed. Reg. at 29,062 (cleaned up). This incorporates not the entire notice, but two passages beginning some 21 pages *after* the single page quoted by the district court. In the first incorporated passage, the FDA argued that warnings "are necessary to alert young people to the dangers of initiating cigar use, as well as to help current cigar smokers better understand and appreciate the health risks of using cigars." NPRM, 79 Fed. Reg. at 23,167. The second passage addressed whether the proposed cigar warnings accurately convey the health risks of smoking cigars. *Id.* at 23,167–70. In both passages, the FDA again focused on effectively conveying information—without serious consideration of how the information might affect smoking.

In any event, the notice would not satisfy section 906(d)(1) even if the Deeming Rule had fully incorporated it. For starters, the passage quoted by the district court failed to disentangle the effects of health warnings from those of age minimums and identification requirements, which involve not simply speech but outright prohibition of certain sales of tobacco products. Moreover, the quoted passage does little more than parrot the governing statutory language, rather than set forth evidence or a reasonable explanation of the likelihood that the proposed warnings would cause smokers to quit and prevent others from starting. Later in the notice, the FDA did elaborate on the various proposed regulations. In doing so, it cited many studies indicating that age minimums and identification requirements would likely reduce underage

smoking. *See* NPRM, 79 Fed. Reg. at 23,160–62. But as for the warning requirements, the FDA said only that "[t]he purpose of health warnings is to help current and potential tobacco users understand and appreciate the serious adverse health consequences associated with tobacco product use and the addictive nature of tobacco products." *Id.* at 23,163; *see also id.* at 23,164 ("FDA believes that the proposed warnings would help both users and nonusers better understand and appreciate these dangers."). This is essentially the same reasoning contained in the final rule, which we have held to be insufficient.

III

Congress required the FDA to consider whether any regulation under section 906(d)(1) would likely affect the number of tobacco users. In promulgating the warning requirements for cigars and pipe tobacco, the FDA failed to satisfy that obligation. We therefore reverse the grant of summary judgment to the FDA and the denial of summary judgment to the plaintiffs. Given our disposition on the merits, we dismiss as moot the plaintiffs' appeal from the denial of their motion for a preliminary injunction. Finally, we remand to the district court for further proceedings consistent with this opinion.

So ordered.