United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued September 23, 2010 Decided December 7, 2010

No. 10-5032

SOTTERA, INC., DOING BUSINESS AS NJOY,
APPELLEE

v.

FOOD & DRUG ADMINISTRATION, ET AL.,
APPELLANTS

Appeal from the United States District Court
for the District of Columbia
(No. 1:09-cv-00771-RJL)

Alisa B. Klein, Attorney, U.S. Department of Justice, argued the cause for appellants. With her on the briefs were *Ronald C. Machen, Jr.*, U.S. Attorney, *Mark B. Stern* and *Samantha L. Chaifetz*, Attorneys, *Ralph S. Tyler*, Chief Counsel, United States Department of Health and Human Services, *Eric M. Blumberg*, Deputy Chief Counsel, and *Karen E. Schifter*, Associate Chief Counsel. *Drake S. Cutini*, Attorney, U.S. Department of Justice, entered an appearance.

William B. Schultz was on the brief for *amici curiae* American Academy of Pediatrics, et al. in support of appellants.

Gregory G. Garre argued the cause for appellee Sottera, Inc. With him on the brief were *Richard P. Bress*, *John R. Manthei*, and *Jessica E. Phillips*.

Deborah M. Shelton and *Christopher M. Loveland* were on the brief for *amici curiae* Smokefree Pennsylvania, et al. in support of appellee.

Daniel J. Popeo, Richard A. Samp, Coleen E. Klasmeier, and *Rebecca K. Wood* were on the brief for *amicus curiae* Washington Legal Foundation in support of appellee.

Before: GARLAND and KAVANAUGH, *Circuit Judges*, and WILLIAMS, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* WILLIAMS.

Opinion concurring in the judgment filed by *Circuit Judge* GARLAND.

WILLIAMS, *Senior Circuit Judge*: Sottera, Inc., which does business as NJOY, is an importer and distributor of "electronic cigarettes" or "e-cigarettes," a product that enables users to inhale vaporized nicotine. The question before us is whether Congress has authorized the Food and Drug Administration ("FDA") to regulate e-cigarettes under the drug/device provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 351 *et seq.*, or under the Family Smoking Prevention and Tobacco Control Act of 2009 (the "Tobacco Act"), Pub. L. 111-31, 123 Stat. 1776. We think that the statutes, properly read in light of the Supreme Court's decision in *FDA v. Brown & Williamson*, 529 U.S. 120 (2000), locate the product under the Tobacco Act.

* * *

Electronic cigarettes are battery-powered products that allow users to inhale nicotine vapor without fire, smoke, ash, or carbon monoxide. NJOY Compl. at 2. Designed to look like a traditional cigarette, each e-cigarette consists of three parts: the nicotine cartridge, the atomizer or heating element, and the battery and electronics. The plastic cartridge serves as the mouthpiece and contains liquid nicotine, water, propylene glycol, and glycerol. *Id*. at 5. The atomizer vaporizes the liquid nicotine, and the battery and electronics power the atomizer and monitor air flow. *Id*. When the user inhales, the electronics detect the air flow and activate the atomizer; the liquid nicotine is vaporized, and the user inhales the vapor. *Id*.

NJOY has imported and distributed e-cigarettes since 2007. *Id*. at 2, 4. The liquid nicotine in each e-cigarette is derived from natural tobacco plants, Decl. of John Leadbeater at 2, and NJOY claims that its product is marketed and labeled for "smoking pleasure," rather than as a therapeutic or smoking cessation product. NJOY Compl. at 2; Decl. of John Leadbeater at 2. On April 15, 2009 the FDA ordered that a shipment of NJOY's e-cigarettes be denied entry into the United States, asserting that the e-cigarettes appeared to be adulterated, misbranded, or unapproved drug-device combinations under the FDCA. April 20, 2009 Notice of FDA Action.

Also in April 2009, another importer and distributor of e-cigarettes, Smoking Everywhere, Inc., sought a preliminary injunction barring the FDA and various officials from denying their products entry into the United States and from regulating e-cigarettes under the drug/device provisions of the FDCA. Smoking Everywhere Compl. at 1-2, 7. NJOY joined as an intervenor-plaintiff and filed its own complaint and request

for a preliminary injunction. NJOY Compl. at 3; Mem. Op. at 7.

Smoking Everywhere and NJOY argued that the FDA can regulate electronic cigarettes, as they propose to market them, only under the Tobacco Act, claiming that the Supreme Court's opinion in *Brown & Williamson* foreclosed FDCA drug/device jurisdiction over tobacco products marketed without claims of therapeutic effect. The district court agreed and granted the injunction. While this appeal was pending, Smoking Everywhere voluntarily dismissed its complaint against the FDA, leaving NJOY as the sole appellee. See NJOY Br. at 4.

When deciding whether to grant a preliminary injunction, a district court must consider four familiar factors: whether "(1) the plaintiff has a substantial likelihood of success on the merits; (2) the plaintiff would suffer irreparable injury were an injunction not granted; (3) an injunction would substantially injure other interested parties; and (4) the grant of an injunction would further the public interest." *Ark. Dairy Co-op Ass'n, Inc. v. U.S. Dep't of Agric.*, 573 F.3d 815, 821 (D.C. Cir. 2009) (citing *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1317-18 (D.C. Cir. 1998)). We review the district court's weighing of these factors under an abuse of discretion standard, but review questions of law *de novo*. *Id.*; see also *Davis v. Pension Benefit Guarantee Corp.*, 571 F.3d 1288, 1291 (D.C. Cir. 2009).

* * *

Under the FDCA, the FDA has authority to regulate articles that are "drugs," "devices," or drug/device combinations. 21 U.S.C. § 321(g)(1) defines drugs to include

> (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals.

21 U.S.C. § 321(g)(1)(B) & (C). The statute defines devices similarly, see 21 U.S.C. § 321(h)(2) & (3); products that are "combination[s] of a drug, device, or biological product" are regulated as combination products, see 21 U.S.C. § 353(g)(1).

Until 1996, the FDA had never attempted to regulate tobacco products under the FDCA (with one exception, irrelevant for reasons discussed below) unless they were sold for therapeutic uses, that is, for use in the "diagnosis, cure, mitigation, treatment, or prevention of disease" under § 321(g)(1)(B). Cf. *Action on Smoking and Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980). But in that year, the FDA changed its long-held position, promulgating regulations affecting tobacco products as customarily marketed, i.e., ones sold without therapeutic claims. See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (Aug. 28, 1996). The agency asserted that nicotine is a drug that affects the structure or function of the body under § 321(g)(1)(C) and that cigarettes and smokeless tobacco were therefore drug/device combinations falling under the FDA's regulatory purview, even absent therapeutic claims. See 61 Fed. Reg. at 44,397, 44,400.

In *FDA v. Brown & Williamson*, the Supreme Court rejected the FDA's claimed FDCA authority to regulate tobacco products as customarily marketed. Looking to the FDCA's "overall regulatory scheme," the "tobacco-specific legislation" enacted since the FDCA, and the FDA's own frequently asserted position, it held that Congress had "ratified

. . . the FDA's plain and resolute position that the FDCA gives the agency no authority to regulate tobacco products as customarily marketed." 529 U.S. at 126, 159.

To fill the regulatory gap identified in *Brown & Williamson*, Congress in 2009 passed the Tobacco Act, Pub. L. No. 111-31, 123 Stat. 1776, 21 U.S.C. §§ 387 *et seq.*, providing the FDA with authority to regulate tobacco products. The act defines tobacco products so as to include all consumption products derived from tobacco *except* articles that qualify as drugs, devices, or drug-device combinations under the FDCA:

> (rr) (1) The term "tobacco product" means any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product . . .
>
> (2) The term "tobacco product" does not mean an article that is a drug under [the FDCA's drug provision], a device under [the FDCA's device provision], or a combination product described in [the FDCA's combination product provision].

21 U.S.C. § 321(rr).

The Tobacco Act itself states that it does not "affect, expand, or limit" the FDA's jurisdiction to regulate products under the drug/device provisions of the FDCA, 21 U.S.C. § 387a(c)(1), and the district court and parties themselves appear to agree that the Tobacco Act did not expand the category of drugs, devices, and combination products subject to FDCA jurisdiction in the wake of *Brown & Williamson*. See Mem Op. 9 n.4. The question before us, therefore, is whether the FDA can regulate electronic cigarettes under the

FDCA's drug/device provisions or whether it can regulate them only under the Tobacco Act's provisions.

The FDA at one point argues that its decision to regulate electronic cigarettes under the FDCA's drug/device provisions is entitled to *Chevron* deference. See *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837 (1984). FDA Br. at 20. But in fact the case does not turn on matters of statutory interpretation. Rather, as the FDA itself argues, the Tobacco Act did not alter the FDA's authority under the FDCA. FDA Br. at 19; FDA Reply Br. at 21. And with respect to tobacco products, the breadth of that authority is governed by the Supreme Court's decision in *Brown & Williamson*. We therefore turn to that case.

* * *

In *Brown & Williamson* the Supreme Court addressed the FDA's regulation of cigarettes and smokeless tobacco products under the FDCA. It began by noting that the FDCA seeks to ensure that the FDA will approve products only if they are safe and effective for their intended use. 529 U.S. at 133. Yet the FDA had itself found that tobacco products are "unsafe," "dangerous," and "cause great pain and suffering from illness." *Id*. at 134 (quoting 61 Fed. Reg. 44,412). If tobacco products were drug/device combinations under the FDCA, the FDA would have no choice but to ban them. *Id*. at 135.

Clearly that could not be the case, the Court reasoned. After all, Congress had declared, in a provision of the U.S. Code then in force, that tobacco was "one of the greatest basic industries of the United States," *id*. at 137 (quoting 7 U.S.C. § 1311(a)), and it had also passed six separate statutes relating to tobacco since 1965. *Id*. at 137-38. See Federal Cigarette

Labeling and Advertising Act, Pub. L. 89-92, 79 Stat. 282; Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, 84 Stat. 87; Alcohol and Drug Abuse Amendments of 1983, Pub. L. 98-24, 97 Stat. 175; Comprehensive Smoking Education Act, Pub. L. 98-474, 98 Stat. 2200; Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. 99-252, 100 Stat. 30; Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. 102-321, § 202, 106 Stat. 394. Finally, citing its decision in *MCI Telecommunications Corp. v. AT&T Co.*, 512 U.S. 218 (1994), the Court noted that "Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion." *Brown & Williamson*, 529 U.S. at 160. So the Court held that the FDA's claim of FDCA jurisdiction failed.

For our purposes, the central question is whether *Brown & Williamson*'s reading of the FDA's authority under the drug/device provisions of the FDCA applies only to tobacco products for which Congress has passed specific regulatory statutes or whether it extends to all tobacco products as customarily marketed. The FDA argues that *Brown & Williamson* takes a statute-specific approach, excluding the FDA from regulating only those tobacco products that at the time of *Brown & Williamson* had been the subject of specific federal legislation. FDA Br. at 14. Though *Brown & Williamson* is not crystal clear, we think the better reading is that the FDA lacks FDCA drug/device authority to regulate all tobacco products marketed without claims of therapeutic effect, i.e., as customarily marketed.

Brown & Williamson's focus was not on the particular products that the six statutes cover or even on the six statutes themselves; at no point did it quote the precise language in which the six statutes identified covered products. Rather, *Brown & Williamson* considered the context of each statute to

show that Congress was actively thinking about "the tobacco problem. " 529 U.S. at 145. In situating the statutes, *Brown & Williamson* found that "[i]n adopting each statute, Congress has acted against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate tobacco absent claims of therapeutic benefit by the manufacturer." *Id*. at 144.

Brown & Williamson concentrated overwhelmingly on the unifying theme of historic FDA policy towards tobacco products—a policy that it saw as undifferentiated except with regard to the presence or absence of claims of therapeutic effect. See, e.g., *id*. at 145 ("[T]obacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions in the Food, Drug, and Cosmetic Act…" (citing Letter to Directors of Bureaus, Divisions and Directors of Districts from FDA Bureau of Enforcement (May 24, 1963))); *id*. at 146 ("In the 73 years since the enactment of the original Food and Drug Act, and in the 41 years since the promulgation of the modern Food, Drug, and Cosmetic Act, the FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims establishing a therapeutic intent on behalf of the manufacturer or vendor" (citing Brief for Appellee (FDA) in *Action on Smoking and Health v. Harris*, 655 F.2d 236 (D.C. Cir. 1980))); *id*. at 146 (noting that the FDA's predecessor agency, the Bureau of Chemistry, stated it lacked authority to regulate tobacco products absent therapeutic claims); *id*. at 155 (quoting the FDA's General Counsel as defining regulatory scope over tobacco products based on therapeutic purpose); *id*. at 158 (citing the FDA Deputy Commissioner stating that FDA's jurisdiction was limited to tobacco products bearing "drug claims"); *id*. at 158 (citing the Commissioner of the FDA stating that FDA's jurisdiction was limited to tobacco products bearing "health claims").

Moreover, discussing the record before Congress in the period when it passed these six statutes, *Brown & Williamson* noted that Congress knew of both "the adverse health consequences of tobacco use" and of "nicotine's pharmacological effects." *Id*. at 138. Nonetheless, Congress "considered and rejected bills that would have granted the FDA" jurisdiction over tobacco products. *Id*. at 144.

In this light, *Brown & Williamson* interprets the six statutes not as a particular carve-out from the FDCA for cigarettes and smokeless tobacco (plus any additional products covered in the six statutes, which the FDA briefs make no effort to itemize), but rather as "a distinct regulatory scheme to address the problem of tobacco and health"—one that Congress intended would "preclude[] any role for the FDA" with respect to "tobacco absent claims of therapeutic benefit by the manufacturer." *Id*. In doing so, Congress also "persistently acted to preclude a meaningful role for *any* administrative agency in making policy on the subject of tobacco and health." *Id*. at 156. As customarily marketed, tobacco products were to remain the province of Congress.

Reflecting on the history and structure of tobacco regulation, *Brown & Williamson* concluded,

> Congress has affirmatively acted to address the issue of tobacco and health, relying on the representations of the FDA that it had no authority to regulate tobacco. It has created a distinct scheme to regulate the sale of tobacco products, focused on labeling and advertising, and premised on the belief that the FDA lacks such jurisdiction under the FDCA. As a result, Congress' tobacco-specific statutes preclude the FDA from regulating tobacco products as customarily marketed.

Id. at 156.

Brown & Williamson therefore did not preclude the FDA from regulating only those products for which Congress had passed specific statutes. Rather, it recognized that Congress had consciously developed a statutory scheme for tobacco and health that distinguished tobacco products as customarily marketed from ones marketed for therapeutic purposes. "Thus, what Congress ratified was the FDA's plain and resolute position that the FDCA gives the agency no authority to regulate tobacco products as customarily marketed." *Id*. at 159.

At oral argument the FDA observed with some justice that the regulatory scheme before the Court in *Brown & Williamson* addressed only cigarettes and smokeless tobacco; it would have us infer that the Court used the incessantly repeated phrase "tobacco products" as a shorthand, confined to the products before the Court (supplemented by whatever additional products were reached by the six statutes). We find no evidence of any such restrictive intent; certainly the Court did not use the familiar economizing form: "cigarettes and smokeless tobacco ('tobacco products')."

The Tobacco Act is wholly consistent with this reading of *Brown & Williamson*. Written to address the regulatory gap that the case identified, the Tobacco Act provides the FDA with regulatory authority over tobacco products without requiring therapeutic claims. Besides leaving the FDA's authority under the drug/device provisions of the FDCA undisturbed, see 21 U.S.C. § 321(rr)(2) & § 387a(c)(1), the act broadly defines tobacco products as extending to "*any* product made *or derived from* tobacco," 21 U.S.C. § 321(rr)(1) (emphasis added). To be sure, this definition could align with a variety of interpretations of *Brown & Williamson*'s scope (including the one FDA proffers here), but our reading is squarely within that range.

The FDA responds that its treatment of the Favor Smokeless Cigarette in 1987 supports its reading of *Brown & Williamson*. FDA Br. at 14-15. We think not. Favor was a small tube containing a nicotine solution, enabling the user to inhale nicotine vapor without smoke. *Id*. at 14. Though the Smokeless Cigarette was marketed without therapeutic claims, the FDA warned Favor that it was an unapproved new drug. *Id*. at 14-15. The FDA's claimed authority over Favor was, however, never challenged or adjudicated in court. Nor did *Brown & Williamson* address the Smokeless Cigarette, perhaps because neither side brought it before the Court (perhaps in turn because the individuals litigating the case were unaware of it). In its argument in *Brown & Williamson*, the FDA stated that "the *only* instances in which the agency had found that tobacco products were drugs involved cases in which there were express market claims of therapeutic value." Pet'rs' Br., *FDA v. Brown & Williamson*, 529 U.S. 120 (2000) (No. 98-1152), 1999 WL 503874 at *37 (emphasis added). In fact, one of the FDA's arguments in *Brown & Williamson* was that the agency was "free to *change* its position" as long as it provided a reasoned justification for the change. *Id*. at *38 (emphasis added). And that would likely have been true—but for the Court's conclusion that Congress had ratified what the Court understood as the FDA's invariable exclusion of tobacco products made without claims of therapeutic effect.

The FDA has also offered a consequentialist argument, namely, that understanding *Brown & Williamson* in this fashion leaves the FDA severely thwarted in any effort to nudge e-cigarettes toward relatively healthful forms (or at least away from relatively unhealthful ones). Whether such a consequentialist argument should play any role in our interpretation of *Brown & Williamson* is questionable, but no matter. In fact the Tobacco Act gives the FDA broad regulatory authority over tobacco products, including, for instance, authority to impose restrictions on their sale, and on

the advertising and promotion of such products, see 21 U.S.C. § 387f(d), to regulate the mode of manufacture of tobacco products, see *id.* § 387f(e), and to establish standards for tobacco products, see *id.* § 387g. To the extent that Congress believed *Brown & Williamson* left an insufficiently regulative environment for cigarettes, smokeless tobacco, cigars, and other tobacco products, it found the Tobacco Act an adequate remedy.

Together, *Brown & Williamson* and the Tobacco Act establish that the FDA cannot regulate customarily marketed tobacco products under the FDCA's drug/device provisions, that it can regulate tobacco products marketed for therapeutic purposes under those provisions, and that it can regulate customarily marketed tobacco products under the Tobacco Act.

* * *

As to NJOY's likelihood of success on the merits, the firm claims that its electronic cigarettes use a liquid nicotine mixture derived from tobacco and that its products are not marketed for therapeutic uses, NJOY Compl. at 5; Decl. of John Leadbeater at 2; the FDA appears not to challenge either claim. Still, the district court noted that the factual record on NJOY is meager and that the FDA may establish that NJOY does in fact make therapeutic claims regarding its electronic cigarettes. Mem. Op. at 25 n. 17. Until such time, the definitional line laid down in *Brown & Williamson* (as we understand it) leaves the FDA without jurisdiction over these products under the FDCA's drug/device provisions. On the merits, then, NJOY is likely to succeed.

We also find that the district court did not abuse its discretion in finding that the balance of harms tips toward

NJOY. In showing irreparable harm, the injury to the party must "be both certain and great; it must be actual and not theoretical." *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). The FDA's refusal to admit NJOY's products into the United States obviously destroyed the firm's ability in the United States to cover its costs for purchase or production of e-cigarettes. The district court's finding that this loss would be irreparable absent an injunction appears entirely reasonable. Mem. Op. at 29. Regarding harm to third parties and to the public interest, the district court observed that the FDA had cited no evidence to show that electronic cigarettes harmed anyone. *Id*. at 30. More significantly, the court rightly found that the FDA has authority under the Tobacco Act to regulate electronic cigarettes, enabling it to mitigate or perhaps extinguish any harm to public health. *Id*. at 31. Given the likelihood of NJOY's success on the merits, the irreparable harm to NJOY's business, and the FDA's unquestioned Tobacco Act authority to mitigate any public harm, the district court did not abuse its discretion in granting the preliminary injunction.

* * *

As we have already noted, the FDA has authority to regulate customarily marketed tobacco products—including e-cigarettes—under the Tobacco Act. It has authority to regulate therapeutically marketed tobacco products under the FDCA's drug/device provisions. And, as this decision is limited to tobacco products, it does not affect the FDA's ability to regulate other products under the "structure or any function" prong defining drugs and devices in 21 U.S.C.§ 321 (g) and (h), as to the scope of which—tobacco products aside—we express no opinion. Of course, in the event that Congress prefers that the FDA regulate e-cigarettes under the FDCA's drug/device provisions, it can always so decree.

The judgment of the district court is

Affirmed.

GARLAND, *Circuit Judge*, concurring in the judgment: Although I join my colleagues in the disposition of this case, I do so based on different reasoning. I do not read *FDA v. Brown & Williamson*, 529 U.S. 120 (2000), as barring the FDA from regulating "electronic cigarettes" under the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, because I do not believe the Supreme Court intended its use of the term "tobacco products" to extend to products that do not contain tobacco. The Tobacco Control Act of 2009, Pub. L. No. 111-31, 123 Stat. 1776, however, expressly extends to products that are merely "derived from" tobacco. Accordingly, at least in the absence of a contrary agency interpretation entitled to *Chevron* deference, I read the Tobacco Control Act as requiring the FDA to regulate products like electronic cigarettes under that Act, rather than under the FDCA.

I

In *Brown & Williamson*, the Supreme Court held that the FDA lacks authority to regulate "tobacco products" under the drug/device provisions of the FDCA, unless those products are marketed with therapeutic claims. 529 U.S. at 144, 158-59. On its face, the natural meaning of the term "tobacco product" is a product -- like cigarettes or chewing tobacco -- that *contains* tobacco. Although it is true that the liquid nicotine in NJOY's electronic cigarettes is *derived from* tobacco, it seems less natural to regard that fact as sufficient to transform NJOY's plastic cartridges -- which contain no tobacco -- into a tobacco product. As NJOY acknowledges, its reading leads to the counterintuitive conclusion that a syringe filled with injectable nicotine is a tobacco product as well. Oral Argument Tr. 40-41.

On many, although not all, occasions on which *Brown & Williamson* used the term "tobacco products," the Court coupled it with an express reference to tobacco or to products that plainly

contain tobacco.[1] At no point did the Court state that the FDA was barred from regulating "nicotine" (or a product containing nicotine but not tobacco) under the FDCA. Thus, the most straightforward reading of the term "tobacco products" is as short-hand for products that contain tobacco. *Compare* 529 U.S. at 155 (describing several congressional statutes as "creating a distinct regulatory scheme *for cigarettes and smokeless tobacco*"), *with id.* at 159 (describing the same statutes as "creat[ing] a distinct regulatory scheme *for tobacco products*") (emphases added).

This reading is consistent with the context in which the Court decided *Brown & Williamson*. In that case, the Court

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[1] *See, e.g.*, 529 U.S. at 126, 127, 128, 129 (using the term "tobacco products" in reference to the FDA's rule concerning the sale of "cigarettes and smokeless tobacco"); *id.* at 129 (describing that rule -- which was limited to cigarettes and smokeless tobacco -- as requiring that a specified statement appear on "all tobacco product packages"); *id.* at 134 (noting that the FDA had found "tobacco products" to cause "tobacco-related illnesses, such as cancer, respiratory illnesses, and heart disease" -- illnesses that the FDA associated with tobacco, not nicotine); *id.* at 142 (noting that "tobacco products" cannot "be safe within the meaning of the FDCA" because, "[a]s the FDA has documented in great detail, cigarettes and smokeless tobacco are an unsafe means to obtaining *any* pharmacological effect"); *id.* at 145 (describing the FDA's 1964 testimony that it lacked authority to label cigarette packages as testimony that it lacked jurisdiction to regulate "tobacco products"); *id.* at 146 (citing, in support of the proposition that the FDA had never before "asserted authority to regulate tobacco products as customarily marketed," the fact that the "FDA has repeatedly informed Congress that cigarettes are beyond the scope of the statute absent health claims").

upheld a challenge to a 1996 FDA rule asserting authority to regulate the sale of cigarettes and smokeless tobacco under the FDCA. 529 U.S. at 126-30 (citing Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396 (Aug. 28, 1996)). Because all of the products at issue in the rule contained tobacco, the Court had no occasion to opine upon the FDA's authority to regulate a product, like electronic cigarettes, that does not. Indeed, although a product indistinguishable from electronic cigarettes had been introduced some ten years earlier -- the "Favor Smokeless Cigarette," which consisted of a small tube containing an inhalable nicotine solution -- there is no indication in *Brown & Williamson* that the Court had ever heard of it. (The FDA had asserted authority to regulate Favor in 1987, notwithstanding that it was marketed without therapeutic claims. Regulatory Letter from FDA to Advanced Tobacco Prods. Inc. (Feb. 9, 1987) (J.A. 425-26)).

But the most telling indication that the holding of *Brown & Williamson* does not extend to electronic cigarettes is that the Court's reasoning does not apply to products that do not contain tobacco. The Supreme Court's chief rationale for its holding had two premises. First, the Court determined that, "if tobacco products were 'devices' under the FDCA, the FDA would be required to remove them from the market." 529 U.S. at 135. It reached this conclusion because the FDA may only approve a product for marketing under the FDCA if it is safe and effective for its intended use, and the FDA had "exhaustively documented" that tobacco products are unsafe for any pharmacological use. *Id.* at 133-35. Second, the Court found that Congress had "foreclosed the removal of tobacco products from the market" through "tobacco-specific legislation" passed subsequent to the FDCA. *Id.* at 137, 143. Thus, the Court concluded: "If they cannot be used safely for any therapeutic

purpose, and yet they cannot be banned, they simply do not fit" within the FDCA's regulatory scheme. *Id.* at 143.

Neither premise holds true for pure nicotine or for a tobacco-free product that delivers nicotine. First, unlike products containing tobacco, which the FDA has found to be associated with "cancer, respiratory illnesses, and heart disease," 529 U.S. at 134-35, the FDA has *not* found that nicotine or tobacco-free products that deliver nicotine are inherently unsafe. To the contrary, the FDA has approved several such products marketed with therapeutic claims, determining that they satisfy the FDCA safety requirements that *Brown & Williamson* determined "tobacco products" could not meet. *See* FDA Br. 16 (noting that the FDA has approved nicotine gums and transdermal patches). Indeed, the FDA states that "it may well be possible for a manufacturer of 'electronic cigarettes' . . . to satisfy the FDCA's safety, effectiveness, and labeling requirements and obtain FDA approval." *Id.*

Second, the "tobacco-specific legislation" the Court found dispositive in *Brown & Williamson* simply does not address products that deliver nicotine but contain no tobacco. As the Court explained, Congress had "directly addressed the problem of tobacco and health through legislation on six occasions since 1965." 529 U.S. at 137.[2] Those statutes impose labeling and

[2]The Court listed the following six statutes: "Federal Cigarette Labeling and Advertising Act (FCLAA), Pub. L. 89-92, 79 Stat. 282; Public Health Cigarette Smoking Act of 1969, Pub. L. 91-222, 84 Stat. 87; Alcohol and Drug Abuse Amendments of 1983, Pub. L. 98-24, 97 Stat. 175; Comprehensive Smoking Education Act, Pub. L. 98-474, 98 Stat. 2200; Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. 99-252, 100 Stat. 30; Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. 102-321, § 202, 106 Stat. 394." 529 U.S. at 137-38.

advertising requirements that "create a distinct regulatory scheme for cigarettes and smokeless tobacco." *Id.* at 155; *see id.* at 143-44, 148-49. Moreover, Congress has declared that "[t]he marketing of tobacco constitutes one of the greatest basic industries of the United States," *id.* at 137 (quoting 7 U.S.C. § 1311(a)), making it "highly unlikely" that the legislature would have subjected the industry to a regulatory regime that could substantially or entirely shut it down, *id.* at 160. "[T]he collective premise of these statutes," the Court said, is "that cigarettes and smokeless tobacco will continue to be sold in the United States." *Id.* at 139.

This "collective premise" does not extend to products, like electronic cigarettes, that contain only nicotine. None of the statutes the Court referenced regulate such products, and the statutory labeling requirements and advertising restrictions the Court cited do not apply to electronic cigarettes. *See* FDA Br. 10, 13-14. Nor can it be said that FDA regulation of a novel product like electronic cigarettes would threaten the health of the American tobacco industry. As NJOY avers, it "imports one hundred percent of its supply of E-cigarettes from overseas manufacturers, and, upon information and belief, there is no domestic manufacturer of E-cigarettes or their component parts." NJOY Compl. ¶ 18 (J.A. 40).

Finally, the *Brown & Williamson* Court also noted that, "[i]n adopting each statute, Congress . . . acted against the backdrop of the FDA's consistent and repeated statements that it lacked authority under the FDCA to regulate *tobacco* absent claims of therapeutic benefit by the manufacturer." 529 U.S. at 144 (emphasis added). "Under these circumstances," the Court concluded, "it is evident that Congress' *tobacco*-specific statutes . . . effectively ratified the FDA's long-held position that it lacks jurisdiction under the FDCA to regulate tobacco

products." *Id.* (emphasis added). But the backdrop of pre-1996 statements to which the Court referred did not include statements that the FDA lacked authority over a product like nicotine, which is merely derived from tobacco. Rather, as the Court's citations make clear, the FDA's statements to Congress referred to its lack of jurisdiction either over "tobacco," *id.* at 145, or over specific products that plainly contain tobacco, like cigarettes, *id.* at 145-46. *See, e.g.*, *id.* at 145 (citing FDA statement that "[t]obacco marketed for chewing or smoking without accompanying therapeutic claims, does not meet the definitions . . . for food, drug, device or cosmetic" in the FDCA). And in fact, as noted above, in 1987 the FDA had asserted authority to regulate a product that is materially indistinguishable from electronic cigarettes -- the Favor Smokeless Cigarette -- apparently without challenge.

In sum, I see nothing in the words, context, or rationale of *Brown & Williamson* that supports interpreting that case as barring the FDA from regulating electronic cigarettes under the drug/device provisions of the FDCA. Although I agree with my colleagues that these considerations do not justify reading *Brown & Williamson* as merely a "carve-out from the FDCA for cigarettes and smokeless tobacco," Slip Op. at 10, they do justify reading it as a carve-out only for products that contain tobacco. *See* 529 U.S. at 144 (holding that Congress intended to "preclude[] any role for the FDA" with respect to "*tobacco* absent claims of therapeutic benefit" (emphasis added)). The Supreme Court had no reason to opine on the status of a product that contains no tobacco, and there is no indication in the opinion that it meant to do so. As my colleagues' opinion rests on the supposition that it did, I cannot join their rationale.

II

But *Brown & Williamson* is not the end of the story. In 2009, Congress passed the Tobacco Control Act, which states: "Tobacco products . . . shall be regulated by the Secretary under this [Act] and shall not be subject to the provisions of [the drug/device subchapter of the FDCA]." 21 U.S.C. § 387a(a). Moreover, unlike *Brown & Williamson*, which used the term "tobacco products" without defining it, the Tobacco Control Act includes a definition: "The term 'tobacco product' means any product made *or derived from* tobacco that is intended for human consumption." 21 U.S.C. § 321(rr)(1) (emphasis added). Because the nicotine in NJOY's electronic cigarettes is "derived from" natural tobacco, NJOY Compl. ¶ 1, it appears that the FDA may regulate it only pursuant to the provisions of the Tobacco Control Act.

The FDA disagrees with this conclusion, contending that the Tobacco Control Act does not narrow the FDA's preexisting authority under the FDCA. In support, agency counsel cites another definitional provision of the Tobacco Control Act, which states that "[t]he term 'tobacco product' does not mean an article that is a drug . . . , a device . . . , or a combination product" under the FDCA. 21 U.S.C. § 321(rr)(2). In the FDA's view, this provision preserves for regulation under the FDCA any product "made or derived from tobacco" that *Brown & Williamson* did not carve out of the FDCA's coverage. And because *Brown & Williamson*'s carve-out did not extend to nicotine-only products, the agency maintains that such products are not necessarily "tobacco products" within the meaning of the Tobacco Control Act.[3]

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[3]Like the FDA, NJOY reads § 321(rr)(2) as leaving the boundary between tobacco products and drugs where it was prior to the passage

There is no doubt that § 321(rr)(2) introduces a note of ambiguity into the analysis. But it is a stretch to conclude that, having just used one express statutory subsection to include products "derived from" tobacco within the definition of "tobacco product," § 321(rr)(1), Congress then immediately employed the next, ambiguous subsection to carve them out again. Rather, it is more likely that § 321(rr)(2) is an expression of Congress' intent to preserve *Brown & Williamson*'s holding that even a product made from tobacco -- for example, a cigarette -- remains a drug, device, or drug/device combination that can be regulated under the FDCA if it is marketed for therapeutic purposes. Hence, the better reading is that § 321(rr)(2) simply makes clear that products made or derived from tobacco that are marketed for therapeutic purposes are not "tobacco products" within the meaning of the Tobacco Control Act, and are therefore subject to regulation under the drug/device provisions of the FDCA.

In the usual circumstance, of course, a judge's view of the "better" reading of a statute administered by an agency is not necessarily dispositive. "If a statute is ambiguous, and if the implementing agency's construction is reasonable, *Chevron* requires a federal court to accept the agency's construction of the statute, even if the agency's reading differs from what the court believes is the best statutory interpretation." *Nat'l Cable & Telecomm. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005) (citing *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 843-44 & n.11 (1984)). In *United States v. Mead Corp.*, 533

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of the Tobacco Control Act. However, because NJOY reads *Brown & Williamson* as having removed nicotine-only products from the FDCA's drug/device authority, it concludes that such products *are* "tobacco products" under the Tobacco Control Act and so may *not* be regulated under the FDCA.

U.S. 218 (2001), however, the Supreme Court held *Chevron* deference appropriate only for statutory interpretations with the "force of law," *id.* at 229, and ruled that an agency's litigation briefs -- unlike, for example, its regulations -- do not warrant such deference, *id.* at 238 n.19. *See also Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212-13 (1988) (declining to accord *Chevron* deference to "agency litigating positions"); *Landmark Legal Found. v. IRS,* 267 F.3d 1132, 1135-36 (D.C. Cir. 2001) (denying *Chevron* deference to an interpretation "developed in litigation").[4]

In this case, there is no agency pronouncement that calls for *Chevron* deference. Other than its briefs, which do not qualify, the only expression of the FDA's view regarding electronic cigarettes is the agency's 2008 detention order barring the importation of NJOY's products. But that order was issued before Congress passed the Tobacco Control Act in 2009 and hence does not construe it at all. "*Chevron* being inapplicable

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[4] As the FDA observes, the Court has accorded deference to briefs in which agencies interpret their own regulations. *See Auer v. Robbins*, 519 U.S. 452 (1997). The Court, however, distinguishes between agency interpretations of regulations and agency interpretations of statutes. *See Couer Alaska, Inc. v. Southeast Alaska Conservation Council*, 129 S. Ct. 2458, 2473 (2009) (finding interpretive memo "not subject to sufficiently formal procedures to merit *Chevron* deference" under *Mead*, but still entitled to deference under *Auer* "because it interprets the agencies' own regulatory scheme"); *see also Mead*, 533 U.S. at 246 (Scalia, J., dissenting) (noting and criticizing the distinction); John F. Manning, *Nonlegislative Rules*, 72 GEO. WASH. L. REV. 893, 943-44 (2004) (observing that *Mead* narrowed the range of agency statutory interpretations that are entitled to *Chevron* deference, while leaving "intact the related but freestanding principle" of *Auer* deference).

here in light of *Mead*, [the court] must decide for [itself] the best reading" of the Act. *Landmark Legal Found.*, 267 F.3d at 1136. And the best reading is to give full effect to the Tobacco Control Act's definition of "tobacco product" as "any product made or derived from tobacco," 21 U.S.C. § 321(rr)(1), as well as to its injunction that "[t]obacco products . . . shall be regulated" under that Act and "shall not be subject to the provisions" of the FDCA, 21 U.S.C. § 387a(a).

III

In the absence of an authoritative agency interpretation, I conclude that, unless a product derived from tobacco is marketed for therapeutic purposes, the FDA may regulate it only under the provisions of the Tobacco Control Act. Accordingly, because NJOY's electronic cigarettes are derived from tobacco, I join my colleagues' disposition. What the result would be were the FDA to offer a contrary statutory interpretation in the form of a regulation, I leave for the day the agency decides to take that step.