Nos. 19-2130 [L], 19-2132, 19-2198, 19-2242

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

AMERICAN ACADEMY OF PEDIATRICS, et al.,
Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,
Defendants-Appellants,

E-LIQUID MANUFACTURING STANDARDS ASSOCIATION, et al.,
Intervenors-Appellants,

CIGAR ASSOCIATION OF AMERICA, et al.,
Appellants.

Appeals from the United States District Court
for the District of Maryland
(No. 8:18-cv-883)

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF VAPOR APPELLANTS AND REVERSAL IN PART

Corbin K. Barthold
Cory L. Andrews
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302
candrews@wlf.org

Counsel for Amicus Curiae
Washington Legal Foundation

January 28, 2020

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 19-2130L Caption: In re: Cigar Association of America, et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

Washington Legal Foundation
(name of party/amicus)

who is amicus curiae, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐ YES ☑ NO

2. Does party/amicus have any parent corporations? ☐ YES ☑ NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐ YES ☑ NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☐NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/ Cory L. Andrews Date: 1/28/2020

Counsel for: Washington Legal Foundation

Print to PDF for Filing

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES:

STATUTES:

Page(s)

OTHER AUTHORITIES:

Page(s)

INTEREST OF *AMICUS CURIAE*[*]

Washington Legal Foundation is a nonprofit, public-interest law firm and policy center with supporters nationwide. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It appears often as *amicus curiae* in important cases on administrative law and the separation of powers. See, e.g., *Seila Law LLC v. CFPB*, No. 19-7 (U.S., review granted Oct. 18, 2019); *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019); *Lucia v. SEC*, 138 S. Ct. 2044 (2018). This appeal involves both of those topics.

Taking to heart the Beltway exhortation never to let a crisis go to waste, the court below used the (concededly alarming) rise in youth vaping as an excuse to seize the FDA's authority to craft public health policy. The court issued a remedy order that effectively doubled as an administrative rulemaking. It should not have done that. In our system of government, the legislature makes the law, and the executive—including agencies such as the FDA—administers it. Emergency or no, the judiciary's only role is to apply the law to cases or controversies.

---

[*] No party's counsel authored any part of this brief. No one, apart from WLF and its counsel, contributed money intended to fund the brief's preparation or submission. All parties have consented to the brief's being filed.

The Anti-Federalist Brutus warned that "every body of men invested with office are tenacious of power." Essays of Brutus No. XI (Jan. 31, 1788). He worried that, invoking fuzzy notions of "equity," the courts would "not confine themselves to any fixed or established rules." *Id.* They would instead construe the law, "in all cases where it can possibly be done," as "will enlarge the sphere of their own authority." *Id.* By this route, Brutus feared, the judiciary could "mould the government" into "almost any shape they please." *Id.*

It is in this light that we must view the trial court's insistence that "extraordinary circumstances" justified, and "equit[y]" enabled, a grab at the other branches' powers. (JA 115-16.) The Framers assured us that Brutus's fears were overwrought. See, e.g., The Federalist No. 78 (Hamilton). If that is so, the trial court's approach must be rejected. A plausible claim of an urgent need is a poor (if seductive) excuse for expanding judicial authority into the realm of policymaking.

WLF urges the Court to vacate the trial court's July 2019 remedy order.

STATEMENT OF THE CASE

In May 2016 the FDA issued a rule deeming e-cigarettes subject to the Tobacco Control Act, 21 U.S.C. § 387 et seq. FDA, *Deeming Tobacco Products Rule*, 81 Fed. Reg. 28,973 (May 10, 2016). The Act requires the maker of a "new tobacco product" to submit to the FDA a premarket approval application. 21 U.S.C. § 387j(a). (Alternatively, the maker can show that the product is substantially equivalent to a product on the market before February 2007.) The application must contain an array of reports on the product and its health effects. E.g., *id.* at § 387j(b)(1).

In the May 2016 deeming rule, the FDA gave companies until May 2018 to submit applications for e-cigarettes that qualify as new tobacco products. 81 Fed. Reg. at 29,011. Then, in August 2017, the FDA issued guidance extending the deadline (at least for e-cigarettes on the market when the initial rule issued) to 2022. (See JA 54.)

A group of doctors and public-health groups filed suit challenging the guidance and its deadline extension. They argued, among other things, that the FDA violated the Administrative Procedure Act by failing to put the guidance through notice and comment. In a May 2019 order granting the plaintiffs' motion for summary judgment, the trial

court accepted this argument and vacated the guidance. (*Id.* at 91-97.) The court then ordered further briefing on the proper remedy. (*Id.* at 97-98.)

In its remedy brief, the FDA contended that the court could "not go beyond vacating the August 2017 guidance." (Dkt. 120 at 2.) The FDA urged the court to let the FDA set a new deadline for itself on remand. (*Id.* at 1.) Strictly in the alternative, the FDA proposed that, should the court feel impelled to set the deadline, it should set it no earlier than May 2020. (*Id.* at 2.) "While perhaps not" what the FDA "would select if permitted to exercise its own discretion," the FDA wrote, a May 2020 deadline would "at least *reduce*" the harmful consequences—such as an "abrupt and massive" removal of vaping products from the market—that a tight deadline would likely produce. (*Id.* at 12 (emphasis added).)

In a July 2019 remedy order, the court acknowledged that the "ordinar[y]" remedy, when a court "reverses agency action," is a "remand to the agency" for further proceedings. (JA 109.) But the court concluded that "extraordinary circumstances"—in particular, an "epidemic-level rise in youth e-cigarette use"—justified its setting a new

deadline itself. (*Id.* at 114-15.) It adopted and imposed the deadline submitted under protest by the FDA—May 2020. (*Id.*)

SUMMARY OF ARGUMENT

A doctor who urges her smoker-patients to switch to e-cigarettes has solid evidence behind her. The Royal College of Physicians has found, for instance, that "the hazard to health arising from long-term vapour inhalation from e-cigarettes . . . is unlikely to exceed 5% of the harm from smoking tobacco." Royal College of Physicians, *Nicotine without smoke: Tobacco harm reduction*, https://bit.ly/2tM8Ji4 (Apr. 28, 2016). And a recent study published in the *New England Journal of Medicine* found that "e-cigarettes were more effective for smoking cessation than nicotine-replacement therapy." Peter Hajek, et al., *A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy*, 380 N. Engl. J. Med. 629, https://bit.ly/2T36bqi (Feb. 14, 2019). For smokers, at least, the advent of e-cigarettes might turn out to be one of the great public-health advances of the new century.

There's a catch. A big one. The same devices that are benefiting smokers are rapidly becoming popular with teens. More than one in four of the high-school respondents in the latest National Youth

Tobacco Survey said they had used e-cigarettes in the last thirty days. CDC, *Youth and Tobacco Use*, https://bit.ly/2Na5l7n (Dec. 10, 2019). The youth vaping rate has more than doubled in the last five years.

Fortunately, this trend is not going unaddressed. Last month Congress passed, and the President signed, a law raising the smoking and vaping age to 21. Sheila Kaplan, *Congress Approves Raising Age to 21 for E-Cigarette and Tobacco Sales*, N.Y. Times, https://nyti.ms/2T36elY (Dec. 19, 2019). The FDA, meanwhile, has just banned the sale of most flavored e-cigarette products. FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization*, https://bit.ly/2Nblnhb (Jan. 2020). A problem arose; the political branches of government—the branches tasked with fixing problems—is acting. One could almost say the system is working.

But not quite. The court below decided that the policymaking must not be left to the policymakers. Not in an emergency.

E-cigarette companies must apply to the FDA for permission to continue selling their products. The application process is complex and onerous, and an e-cigarette maker that fails to submit a timely

application will have to pull its product from the market. In part to ensure that e-cigarettes remain available to people trying to stop smoking, the FDA in 2017 issued guidance extending the application deadline from 2018 to 2022. In a May 2019 merits order, the trial court concluded that the guidance was a legislative rule requiring notice and comment under the APA. (JA 97.) The court seemed poised to remand the matter to the FDA, which could set a new deadline in guidance that "w[ould], of course, have to adhere to the notice and comment requirements." (*Id.*) But then, in a July 2019 remedy order, the court changed course. Having concluded that the deadline is a legislative rule, the court now decided to do the legislating itself. It set the deadline as May 2020. Although the judge acknowledged that it is "extraordinary" to engage in such rulemaking from the bench, he believed that the "epidemic-level rise in youth e-cigarette use" justified his action. (*Id.* at 114.)

It did not. A court reviews agency action only as an *appellate* tribunal. After vacating an agency's decision, therefore, a court should remand the matter to the agency for further proceedings. The trial court cited deviations from the remand-only rule, but in all of them the

agency appeared to be acting in bad faith. That is not this case. The court also cited a mandamus clause in the APA, but that provision does not apply, because selecting a deadline is not a ministerial act.

There are good reasons for the remand-only rule. Judges are not democratically elected, and they are not policy experts. Agencies are different. They sit within a democratic branch. Before making decisions, they can gather information—in this instance, the FDA *must* gather it, through notice and comment—from a wide range of sources. And they have entire staffs of experts.

The trial court did not acknowledge its institutional deficits. It dove headfirst into a policy matter that touches on deep questions of science, economics, statistics, public health, and moral principle. What's worse, its order addressing these questions is perfunctory. Were the order treated as an agency's final decision, it would be struck down as arbitrary and capricious. The order itself shows that in an emergency, it is more, not less, important that policymakers, rather than judges, be in charge. A crisis is an especially bad time to ditch accountability and expertise.

ARGUMENT

I. A DISTRICT COURT ASSESSING AGENCY ACTION IS A COURT OF REVIEW, NOT OF FIRST VIEW.

In its May 2019 merits order, the trial court quoted a passage from *Brown & Williamson Tobacco Corp. v. Food & Drug Administration*, 153 F.3d 155, 176 (4th Cir. 1998), affirmed, 529 U.S. 120 (2000):

> This is not a case about whether additional or different regulations are needed to address legitimate concerns about the serious health problems related to tobacco use, and particularly youth tobacco use, in this country. At its core, this case is about who has the power to make this type of major policy decision.

Brown & Williamson was about the division of power between Congress and an agency, whereas the present appeal is about the division of power between an agency and a court. With that caveat made, however, and with a reference to the dangers of youth vaping inserted, the passage becomes an apt description of the question that faced the trial court as it turned to the matter of remedy.

The answer to that question is clear: it is for the FDA, on remand, using the notice-and-comment process, and not a court, in chambers, to make the "major policy decision" inherent in the setting of a new

premarket approval application deadline. The FDA has the tools to decide what "different regulations are needed." A court emphatically does not.

A. After Setting Aside A Good-Faith Agency Action, A Court Must Remand.

"The normal remedy," when a federal court concludes that an agency has erred, "is a remand for further proceedings in which the agency may attempt to buttress its original policy choice with more extensive analysis and explanation." Stephen G. Breyer, et al., *Administrative Law and Regulatory Policy* 347 (8th ed. 2017). See, e.g., 5 U.S.C. § 706(2) (empowering a court only to "set aside" an unlawful agency action); *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) ("If the record before the agency does not support the agency action, . . . the reviewing court is not generally empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry."); *Austin v. Jackson*, 353 F.2d 910, 912 (4th Cir. 1965) ("Without any reason given for the [agency's conclusion] this court has no choice but to remand.").

Only in "rare circumstances" may a court do more than simply remand to the agency. *Fla. Power*, 470 U.S. at 744. The cases raised by

the plaintiffs, and relied on by the court below, show that a court may do so when an agency has repeatedly failed to obey the law or follow proper procedure. *Cobell v. Norton*, 240 F.3d 1081, 1109 (D.C. Cir. 2001), for example, affirms an award of injunctive relief aimed at remedying an agency's "record of . . . resistance to the fulfillment of its legal duties." (See Dkt. 120 at 3 n.2 (discussing other cases).) The authorities cited show that a court may issue an injunction aimed at stamping out a pattern of administrative recalcitrance. They do not suggest that a court may use an injunction to craft public policy in the first instance. Which is not surprising, because it can't. "A court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). If an agency is acting in good faith, a court may not use the remedy stage to do the agency's work on the agency's behalf. Not even when it *really* wants to.

When conducting "judicial review of agency decision making," the district court's "factfinding capacity" is "typically unnecessary." *Fla. Power*, 470 U.S. at 744. That is because courts, even trial courts, review agency action *on appeal*. The district court undertakes "the identical

task" as the circuit court. *Id.* This is one reason why "the Hobbs Act and other jurisdictional provisions" place "initial review in the courts of appeals"—to "avoid the waste attendant upon this duplication of effort." *Id.*

True, an appellate court can at times use a writ of mandamus to do more than just remand. And sure enough, the APA contains a mandamus provision, 5 U.S.C. § 706(1), that empowers a court to "compel agency action unlawfully withheld or unreasonably delayed." This clause *sounds* like it might support the remedy order, and the trial court indeed waved a hand at it. (JA 115.) But it is *just* a mandamus provision. "Just like the traditional mandamus remedy from which [it] is derived, claims to compel agency action" under §706(1) "are limited to enforcement of a specific, unequivocal command, over which an official has *no* discretion." *City of New York v. U.S. Dep't of Defense*, 913 F.3d 423, 432 (4th Cir. 2019) (emphasis added). Everyone here "agree[s] that the FDA *has* some discretion" in setting the premarket approval application deadline. (JA 73 (emphasis added).) So §706(1) does not apply.

B. The Remand-Only Rule Keeps The Judiciary Within Its Narrow, Proper Role.

The remand-only rule ensures that agencies, not the courts, do the policymaking.

Judges are not, and are not equipped to be, policymakers. They "are not part of either political branch of the Government," *Chevron v. NRDC*, 467 U.S. 837, 865 (1984); and they "lack both expertise and information" to resolve "policy disagreements," *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 66 (2004). They must, therefore, resist the urge to impose their "personal policy preferences." *Chevron*, 467 U.S. at 865. Wading into matters of public policy "erodes . . . the integrity of the judiciary." *Westvaco Corp. v. Utd. Paperworkers Int'l Union*, 171 F.3d 971, 978 (4th Cir. 1999).

"[I]t is entirely appropriate," by contrast, for "an agency to which Congress has delegated policy-making responsibilities" to "make such policy choices." *Chevron*, 467 U.S. at 865. To begin with, the agencies have a modicum of democratic legitimacy—more, at any rate, than the courts do. *Id.* They are also required to consider a wider range of viewpoints—especially where, as here, the agency must conduct notice-and-comment rulemaking under 5 U.S.C. § 553. "The notice-and-

comment procedure encourages public participation in the administrative process and educates the agency, thereby helping to ensure informed agency decisionmaking." *Chocolate Mfrs. Ass'n of U.S. v. Block*, 755 F.2d 1098, 1103 (4th Cir. 1985).

A comment period is not just "for show." *N.C. Growers' Ass'n, Inc. v. Utd. Farm Workers*, 702 F.3d 755, 772 (4th Cir. 2012) (Wilkinson, J., concurring). The agency must keep an "open-minded attitude." *Chocolate Mfrs.*, 755 F.2d at 1103. It must "give adequate consideration to the evidence and analysis submitted by private parties." Breyer, et al., supra, at 347. It must then "develop an evidentiary record" and "explain in considerable detail [its] reasoning." *Id.*; see also *State Farm*, 463 U.S. at 43.

The notice-and-comment protocol gives an agency powerful institutional advantages in addressing what's known as the knowledge problem—the fact that useful information is dispersed throughout society. See F.A. Hayek, *The Use of Knowledge in Society*, 35 Am. Econ. Rev. 519 (1945). "The goal of notice-and-comment rulemaking" is "to fill gaps in knowledge and to see what might have been overlooked." Cass R. Sunstein, *The Cost-Benefit Revolution* 88 (2018). "If the agency has

inaccurately assessed the costs and benefits, public participation can and often will supply a corrective." *Id*. The agencies, unlike the courts, can "collect dispersed knowledge" and "bring it to bear on official choices." *Id*.

What's more, the agencies have the expertise that the courts lack. That is especially true of agencies that address scientific or technical matters—such as the FDA. The FDA's work "requires deep knowledge of the human body and the biological effects of the substances we ingest." J. Harvie Wilkinson III, *Assessing the Administrative State*, 32 J.L. & Pol. 239, 246 (2017). And this case requires more yet. The FDA is here called on (1) to understand, assess, and compare the relative health effects of cigarettes and e-cigarettes; (2) to gather and study statistics on (a) the prevalence of youth vaping and (b) the prevalence, and relative effectiveness, of vaping as an approach to smoking cessation; (3) to assess the vaping industry's capacity to compile and submit premarket approval applications; and then (4) to weigh the costs and benefits of moving the application deadline forward or backward. These complex issues are best handled by the agency, with its teams of doctors, scientists, statisticians, and economists, and not by a generalist

judge, however wise, with his law degree and his clerks. That is precisely why the APA "protect[s] agencies from undue judicial interference with their lawful discretion." *Norton*, 542 U.S. at 66.

The remand-only rule is the natural corollary of the standard by which courts review agency action. A court's "review of an agency's final decision is narrow." *N.C. Growers*, 702 F.3d at 764; see 5 U.S.C. § 706(2). The court is to focus simply on whether the agency "consider[ed] . . . the relevant factors" and avoided "clear error[s] of judgment." 702 F.3d at 764. Again, the court "*is not to substitute its judgment for that of the agency*." *State Farm*, 463 U.S. at 43 (emphasis added). The confined judicial-review standard and the remand-only rule are the same principle operating at two different times. They each tell the court not to snatch for itself the job of "resolving the competing interests which Congress . . . left to be resolved by the agency." *Chevron*, 467 U.S. at 865-66.

II. THE DISTRICT COURT ERRED IN CRAFTING POLICY ON THE AGENCY'S BEHALF.

The court below was not trying to rein in an unruly agency. On the contrary, the court concluded that the FDA is not "a puppet to the tobacco industry"; that it had "made a commendable record"; and that it

had "outlined" the "coordinated approach" it is taking to "deal with th[e] [youth-vaping] public health crisis." (JA 110, 112, 116.)

What attracted the court's attention was not administrative defiance, but public policy. Congress and the FDA are currently grappling with how to balance, on the one hand, the benefits vaping can provide to smokers trying to quit cigarettes and, on the other, the risks vaping poses to the young. But the court had opinions of its own. It had thoughts about the evidence on vaping and smoking cessation, about the diligence of the vaping industry in preparing premarket approval applications, about the magnitude of the youth-vaping problem, and about much else. (*Id.* at 113-14.) Rather than let the agency bring its expertise to bear on these matters—after conducting the required notice-and-comment process (contra FDA AOB at 23)—the court decided to weigh in on them for itself. Its ruling stands on assumptions, sometimes stated, sometimes not, about the relative health dangers of smoking versus vaping; the degree to which e-cigarettes help smokers trying to stop; the causes of the rise in teen vaping; the rate at which teen vaping *leads* to smoking, and the rate at which it *replaces* it; the vaping industry's capacity to quickly submit quality premarket

approval applications, and the FDA's capacity to quickly process them; the impact of driving small businesses from the vaping market; and, beyond all, the proper balance to be struck between the needs and health of smokers and the needs and health of teens. The court did not resist "interfer[ing] with [the agency's] lawful discretion," *Norton*, 542 U.S. at 66; it all but leapt at the chance to do so. It did not "avoid judicial entanglement" in policy questions, *id.*; it issued a white paper masquerading as a legal opinion.

Not only did the court improperly "substitute its judgment for that of the agency," *State Farm*, 463 U.S. at 43; it did so with just a few pages of thinly supported assertions. Ironically, if an agency tried to pass the court's order off as a final decision, it would almost certainly be rebuked. Take for example the court's claim about "the uncertainty . . . of e-cigarettes as smoking cessation devices." (JA 114.) The court, to be sure, cited the FDA's brief for this point (a problematic thing to do, as we'll see); but it offered no data and no analysis of its own. An agency must "offer [a] rational connection between facts and judgment." *State Farm*, 463 U.S. at 56. An agency that simply declares, as the court did, that "there is evidence [both] for and against" something (JA 113) has

failed to make that connection; it has failed to "*examine* the relevant data" and "*articulate* a satisfactory explanation for its action." 463 U.S. at 43 (emphasis added).

Consider too the court's comfort with the notion that imposing a tight deadline will put all but "some of the more successful [vaping] companies" out of business. (JA 113.) The court seemed to treat the *survival* of some competitors as by itself justifying the *demise* of many others. *Id.* It never addressed why the destruction of many small businesses was an acceptable byproduct of its decision. An agency may not proceed this way. Before imposing a regulation that forces businesses to close, an agency must set forth an extensive explanation for its action. See *United States v. Nova Scotia Food Products Corp.*, 568 F.2d 240, 253 (2d Cir. 1977) ("[T]he comment that to apply the [agency's rule] would destroy [the objecting business's] commercial product was neither discussed nor answered. We think that to sanction silence in the face of such vital questions would be . . . less than adequate safeguard against arbitrary decision-making.").

The trial court justified stepping in front of the FDA by announcing that "prompt action is necessary" to address a "mounting

public health crisis." (JA 114.) By this the court meant that prompt action was necessary *by it*. Apparently Congress and the FDA could not move quickly enough, by the court's lights, to address the recent rise in teen vaping. But that was not the court's decision to make. It is for the political branches to declare an emergency, to assess how dire it is, and to take prompt action. Indeed, Congress and the FDA *have* moved quickly to address the "clear public health emergency" identified by the court (*id.*); Congress passed the new age restriction, and the FDA imposed the flavor ban. But even if they hadn't budged, there was no ground for the trial court to take the wheel. A court may not conclude that, because *it* thinks the democratic branches should have found some matter more important and pressing, the separation of powers may be discarded.

It is no answer that the trial court at times relied on suggestions or material supplied by the FDA's lawyers. "[T]he courts may not accept appellate counsel's *post hoc* rationalization for agency action." *State Farm*, 463 U.S. at 50. Still less, then, may they let the agency's lawyers guide them in formulating *new* policy on an agency's behalf. "[T]he focal point for judicial review should be the administrative record already in

existence, not some new record made initially in the reviewing court." *Fla. Power*, 470 U.S. at 743. If the record is inadequate, the proper course is not for the trial judge and the agency's lawyers to collaborate on calling an audible at the courthouse; it is for the judge to "remand for further proceedings" at the agency. Breyer, et al., supra, at 347.

CONCLUSION

The trial court's July 2019 remedy order should be vacated, so that the trial court can remand to the FDA for notice-and-comment rulemaking conducted in accord with 5 U.S.C. § 553.

January 28, 2020

Respectfully submitted,

/s/ Cory L. Andrews

Corbin K. Barthold
Cory L. Andrews
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Ave., NW
Washington, DC 20036
(202) 588-0302
candrews@wlf.org
Counsel for Amicus Curiae Washington Legal Foundation

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT
Effective 12/01/2016

No. 19-2130 [L] **Caption:** In re: Cigar Association of America, et al.

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT

Type-Volume Limit, Typeface Requirements, and Type-Style Requirements

Type-Volume Limit for Briefs: Appellant's Opening Brief, Appellee's Response Brief, and Appellant's Response/Reply Brief may not exceed 13,000 words or 1,300 lines. Appellee's Opening/Response Brief may not exceed 15,300 words or 1,500 lines. A Reply or Amicus Brief may not exceed 6,500 words or 650 lines. Amicus Brief in support of an Opening/Response Brief may not exceed 7,650 words. Amicus Brief filed during consideration of petition for rehearing may not exceed 2,600 words. Counsel may rely on the word or line count of the word processing program used to prepare the document. The word-processing program must be set to include headings, footnotes, and quotes in the count. Line count is used only with monospaced type. See Fed. R. App. P. 28.1(e), 29(a)(5), 32(a)(7)(B) & 32(f).

Type-Volume Limit for Other Documents if Produced Using a Computer: Petition for permission to appeal and a motion or response thereto may not exceed 5,200 words. Reply to a motion may not exceed 2,600 words. Petition for writ of mandamus or prohibition or other extraordinary writ may not exceed 7,800 words. Petition for rehearing or rehearing en banc may not exceed 3,900 words. Fed. R. App. P. 5(c)(1), 21(d), 27(d)(2), 35(b)(2) & 40(b)(1).

Typeface and Type Style Requirements: A proportionally spaced typeface (such as Times New Roman) must include serifs and must be 14-point or larger. A monospaced typeface (such as Courier New) must be 12-point or larger (at least 10½ characters per inch). Fed. R. App. P. 32(a)(5), 32(a)(6).

This brief or other document complies with type-volume limits because, excluding the parts of the document exempted by Fed. R. App. R. 32(f) (cover page, disclosure statement, table of contents, table of citations, statement regarding oral argument, signature block, certificates of counsel, addendum, attachments):

☑ this brief or other document contains 4,144 [*state number of*] words

☐ this brief uses monospaced type and contains _____ [*state number of*] lines

This brief or other document complies with the typeface and type style requirements because:

☑ this brief or other document has been prepared in a proportionally spaced typeface using Microsoft Word 2010 [*identify word processing program*] in 14-point Century Schoolbook [*identify font size and type style*]; **or**

☐ this brief or other document has been prepared in a monospaced typeface using _____ [*identify word processing program*] in _____ [*identify font size and type style*].

(s) Cory L. Andrews

Party Name Washington Legal Foundation

Dated: 1/28/2020

CERTIFICATE OF SERVICE

I hereby certify that on this 28th day of January, 2020, a true and correct copy of the foregoing was filed with the Clerk of the United States Court of Appeals for the Fourth Circuit via the Court's CM/ECF system, which will send notice of such filing to all counsel who are registered CM/ECF users.

/s/ Cory L. Andrews
CORY L. ANDREWS
Counsel for Amicus Curiae
Washington Legal Foundation