IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, *et al.*,	)	
	)	
	)	
Plaintiffs,	)	Civil Action No.
	)	16-1460 (APM)
v.	)	
	)	
FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
	)	
	)	
Defendants.	)	
_____	)	

BRIEF OF *AMICUS CURIAE* CAUSE OF ACTION INSTITUTE
IN SUPPORT OF PLAINTIFFS'
MOTION FOR PARTIAL SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations and Administrative Materials

INTEREST OF *AMICUS CURIAE*

Amicus Curiae Cause of Action Institute ("CoA Institute"), is a 501(c)(3) nonpartisan, nonprofit strategic oversight group committed to ensuring that government decision-making is open, honest, and fair. In carrying out its mission, CoA Institute uses various investigative and legal tools to educate the public about the importance of government transparency and accountability. CoA Institute also frequently represents third-party plaintiffs in actions against the federal government, seeking to scale back regulatory abuses and overreach. CoA Institute believes small business entrepreneurship should not be harmed in the regulatory process. It is essential that agencies follow statutorily-mandated procedures in promulgating rules and regulations. This helps ensure that the regulatory process adheres to the intent of Congress, is fair, and does not unduly burden small business concerns.

Pursuant to Local Rule 7.0(o), CoA Institute certifies that it is not owned, in full or in part, by any parent corporation or publicly held corporation. Furthermore, CoA Institute received no monetary contribution, from a party or any other person, for filing this brief. Finally, counsel for CoA Institute authored this brief in full.

INTRODUCTION

The effectiveness of warning labels on tobacco products has been discussed and debated since the Surgeon General's Warning of 1964 first appeared on cigarette containers. In 2009, Congress expanded the Food and Drug Administration's ("FDA") authority to regulate such labeling, including for non-cigarette tobacco products, but with an important caveat: the agency must do its homework and show how any new regulatory scheme will affect tobacco usage. In the matter at issue here, the FDA has stated that there is no reliable evidence on which to base its rulemaking and, thus, it cannot fulfill the statute's requirements. To allow the FDA to skirt the will of Congress would set an unwieldy and dangerous precedent leading to other agencies ignoring statutory requirements. This case is not about the virtues or efficacy of warning labels on tobacco products. It is about holding an agency accountable when it violates the orders of the Legislature and fails to conduct required statutory analysis. American consumers and small business owners deserve more from their regulatory agencies.

ARGUMENT

I. The FDA Has Ignored Congress's Mandate to Analyze Warning-Label Efficacy

In 2009, Congress delegated to the FDA the authority to promulgate regulations concerning the size, location, and content of warning labels on a variety of tobacco products. *See* Family Smoking Prevention and Tobacco Control Act ("FTCA"), Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. ch. 9). Congress, however, granted this authority with important caveats:

> 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 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) (emphasis added). Carefully examining the language, one first finds that the agency "may" promulgate regulations "if" it determines such regulations are necessary for the public health. Then, this finding "shall be determined with respect" to the "risks and benefits" of American consumers. Congress then goes on to add two additional elements—increased or decreased likelihood of new or continuing tobacco use—that also must be considered. The Supreme Court has consistently held that use of the word "may" along with "shall" is critical to statutory interpretation.

> The word 'shall' usually connotes a requirement, unlike the word 'may,' which implies discretion . . . for when a statute distinguishes between 'may' and 'shall,' the latter generally *imposes a mandatory duty*.

Kingdomware Tech., Inc. v. United States, 136 S. Ct. 1969, 1971, 1977 (2016) (comparing *Lexecon Inc. v. Milberg Weiss Bershard Hynes & Leach*, 523 U.S. 26, 35 (1998) (recognizing that "shall" is "mandatory" and "normally creates an obligation impervious to judicial discretion"), with *United States v. Rodgers*, 461 U.S. 677, 706 (1983) (explaining that "[t]he word 'may,' when used in a statute, usually implies some degree of discretion")) (emphasis added); *see Bennett v. Spear*, 520 U.S. 154, 175 (1997) ("And any contention that the relevant provision . . . is discretionary would fly in the face of its text, which uses the imperative 'shall."). The D.C. Circuit has fully adopted the Supreme Court's approach, especially when both "shall" and "may" are used together.

> Ordinarily, legislation using "shall" indicates a mandatory duty while legislation using "may" grants discretion . . . [W]hen a statutory provision uses both "shall" and "may," it is a fair inference that the writers intended the ordinary distinction.

Anglers Conversation Network v. Pritzker, 809 F.3d 664 (D.C. Cir. 2016); *see Appalachian Voices v. McCarthy*, 989 F. Supp. 2d 30, 54 (D.D.C. 2013); *Kakeh v. United Planning Org., Inc.*, 655 F. Supp. 2d. 107, 123 (D.D.C. 2009) ("It is well-settled that when a statute uses the term 'shall,' it creates a mandatory duty.").

Thus where, as here, the words "may" and "shall" are used in conjunction, Congress makes it clear that one function—in this case, promulgating the rule—is discretionary, while the other—analyzing risks and benefits—is mandatory. To summarize: the FDA had the *option* of whether or not to engage in the rulemaking, but once it did, it had the mandatory *duty* to take into account risks and benefits.

In its rulemaking papers, the FDA openly admitted that it failed to fulfill its statutory duties. *See* Food & Drug Admin., Final Rule Deeming Tobacco Products to Be Subject to the Federal

Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974, 29,075 (May 10, 2016) ("[W]e cannot predict the size of these [labeling] benefits at this time."); Food & Drug Admin., Final Regulatory Impact Analysis: Deeming Tobacco Products to be Subject to the Food, Drug, and Cosmetic Act at 44 (May 2016) [hereinafter FRIA]; *id.* at 59 ("Reliable evidence on the impacts of warning labels, premarket review, and marketing restrictions on users of cigars . . . does not, to our knowledge, exist."); Food & Drug Admin., Proposed Rule Deeming Tobacco Products to be Subject to the Federal Food Drug, and Cosmetic Act, 79 Fed. Reg. 23,142, 23,165 (Apr. 25, 2014) [hereinafter Proposed Rule] ("[T]here has not yet been extensive research regarding the effectiveness of health warnings on tobacco products other than cigarettes[.]"). Instead, the FDA merely speculated about the efficacy of its new labeling edicts. FRIA at 64 ("The addition of warning statements . . . *may* reduce misconceptions about their health risks and addictiveness.") (emphasis added); *id.* at 122 (discussing how consumers "could" react to the current labeling regime in a certain way); Proposed Rule, 79 Fed. Reg. at 23,196 ("Consumers *may* act on this information by reducing their use of tobacco products.") (emphasis added).

The case at hand is directly covered by the mandatory precedent in *Chamber of Commerce of the United States v. Securities & Exchange Commission*, 412 F.3d 133 (D.C. Cir. 2005). There, the SEC "claimed it was without a 'reliable basis for determining how [mutual] funds would choose to satisfy the [proposed regulatory condition] and therefore it [was] difficult to determine the costs associated[.]'" *Id*. at 143 (original alterations modified). This is almost identical to the FDA's contention that it cannot assess the impact of labeling.

> Reliable evidence on the impacts of warning labels, premarket review, and marketing restrictions on users of cigars . . . does not, to our knowledge, exist. Estimating the effects of the final rule on users of these products would require extrapolating from the experience of other products and other regulations that provide similar information sets and institutional changes. This extrapolation

> would also require evidence on the baseline practices, knowledge, and attitudes toward risk of current and potential users of newly deemed products

FRIA at 62. While the D.C. Circuit conceded in *Chamber* that data limitations may make more precise measurements difficult, it nevertheless recognized that those limitations cannot "exclude the Commission from its statutory obligation to determine as best it can the economic implications of the rule it has proposed." *Chamber*, 412 F.3d at 143.[1] The same obligation applies to the FDA here.

The FTCA's requirements are well-defined in analogous case law. Whenever an agency promulgates a new rule, it "must give adequate reasons for its decisions." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). Government rule-makers "'must examine the relevant data and articulate a satisfactory explanation for [their] action including a rational connection between the facts found and the choice made.'" *Id*. (quoting *Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Furthermore, "where the agency has failed to provide *even that minimal level of analysis*, its action is arbitrary and capricious and so cannot carry the force of law." *Id*. (citing 5 U.S.C. § 706(2)(a) and *State Farm*, 463 U.S. at 42–43) (emphasis added). This is vital when the Legislature specifically orders an agency to conduct detailed analysis in the regulation's enabling statute, as Congress wisely did here. 21 U.S.C. § 387f(d)(1). While the procedural background in *Encino Motorcars* was different—the agency was reinterpreting its own rule—the same logic and longstanding principles of agency rulemaking apply: agencies must explain their rationale and back it up with sound science. The D.C. Circuit

[1] As the D.C. Circuit further explained, "uncertainty may limit what the Commission can do, but it does not excuse the Commission from its statutory obligation to do what it can to apprise itself—and hence the public and the Congress—of the economic consequences of a proposed regulation before it decides whether to adopt the measure." *Chamber*, 412 F.3d at 144.

has found such statutory language to be particularly stringent when it requires the agency conduct a risk-benefit, or cost-benefit, analysis. *See, e.g., Bus. Roundtable v. Sec. & Exch. Comm'n*, 647 F.3d 1144 (D.C. Cir. 2011) (finding the SEC's failure to analyze the efficacy of a rule was "arbitrary and capricious"); *Pub Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004) (holding a rule arbitrary and capricious because the agency failed to consider factors required under the organic statute).

Here, the FDA asserts that this Court can simply take the agency's word for the scientific basis of its new labeling regulations. Congress left no doubt as to the requirements of the FTCA. 21 U.S.C. § 387f(d)(1) ("shall be determined"). The agency in *Kingdomware* similarly attempted to "evade" its mandatory duties, arguing it had already fulfilled them in a different form. *Kingdomware*, 136 S. Ct. at 1976. Not so, said the Supreme Court. *Id*. at 1976 ("The Act does not allow the Department to evade [its statutory duties] on the ground that it has already met its . . . goals[.]") Therefore, just as in *Kingdomware*, the FDA "must first apply" the required statutory analysis. *Id*. at 1977. It has failed to do so. Furthermore, just as in *Chamber*, the FDA cannot simply evade statutory requirements because the data present challenges. *Chamber*, 412 F. 3d at 362. This Court should vacate and remand the rule for further analysis.

CONCLUSION

The FDA can fulfill Congress's edict by preparing a new study using existing data, engaging focus groups, conducting a lab-based study, and/or even hiring outside experts. The agency surely has wide discretion in how it goes about its analysis, but it still must do *something* to comply with the law.

For the reasons discussed above, *Amicus* CoA Institute respectfully requests that the Court vacate and remand the FDA's final rule.

Dated: October 10, 2017

Respectfully submitted,

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