Image: John Takai

Caught in the Crosshairs? A Regulatory Relief Fight

A challenge to the President's "two-for-one" limit on federal regulations could expand tobacco regulations.

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What can the President do to reduce costs to businesses seeking to comply with federal regulations? That is at issue in Public Citizen, Inc., et al. v. Trump, et al., No. 1:17-cv-253 (D.D.C.), a challenge to President Trump's "two-for-one" executive order.

The case has broader implications for various federal agencies and their regulations, including tobacco regulations. The case could implicate the extent of the Food & Drug Administration's (the "FDA") regulation under the Family Smoking Prevention and Tobacco Control Act (the "TCA").

EXECUTIVE ORDER 13771

On January 30, 2017, President Trump issued Executive Order 13771, entitled: "Reducing Regulation and Controlling Regulatory Costs" (hereafter, the "Executive Order"). The purpose of the Executive Order is to manage the regulatory and compliance costs and burdens imposed on private parties.

The Executive Order's main requirements are that:

- *a federal agency proposing or promulgating a new regulation must identify at least two existing regulations for repeal;*
- *any new costs associated with a federal agency's new regulation must be offset by eliminating costs associated with at least two existing regulations; and*
- *a federal agency's incremental costs (for issuing new regulations and repealing regulations) are annually capped.*

The Office of Management and Budget (OMB) has since issued guidances for implementing the Executive Order: an interim guidance dated February 2, 2017, and a final guidance dated April 5, 2017. The guidances limit the Executive Order's application to "significant" federal regulatory actions and guidance documents, meaning that they have an annual effect of $100 million or more on the economy or meet certain other criteria.

Eight days after the Executive Order's issuance, a complaint was filed challenging it and the OMB guidances in the U.S. District Court for the District of Columbia.

PLAINTIFFS' INITIAL COMPLAINTS

The plaintiffs are Public Citizen, Inc.; the Natural Resources Defense Council, Inc.; and the Communications Workers of America, AFL-CIO. The initial complaint named the President, the United States, the OMB director, and the heads of thirteen federal agencies as defendants. In the initial complaint filed February 8, 2017, the plaintiffs forwarded claims that:

- *the Executive Order violates the constitutional principle of the separation of powers;*
- *the Executive Order violates the "Take Care Clause" under Article II, § 3 of the Constitution (requiring that the President "take care that the laws be faithfully executed");*
- *federal agencies lack authority to follow the Executive Order;*
- *OMB lacks authority to issue guidance concerning the Executive Order; and*
- *the Executive Order violates the Administrative Procedure Act.*

The plaintiffs asked the Court to declare the Executive Order and OMB guidances unlawful and to enjoin the defendants from implementing or complying with them.

IMPLICATIONS FOR FDA TOBACCO REGULATION

Although the case is not directly focused on tobacco regulation, it could have implications for the FDA's regulation of the tobacco industry. A number of tobacco-focused organizations have been participating in the case as *amici curiae* in support of the plaintiffs. Among them are the Public Health Law Center, the American Academy of Pediatrics, the Campaign for Tobacco-Free Kids, the Public Health Advocacy Institute, the Public Health & Tobacco Policy Center, and the Truth Initiative.

In a brief filed with the Court, these organizations have argued that the Executive Order deters the FDA from issuing new regulations and threatens the existence of existing regulations under laws including the TCA.

For instance, these organizations contend that the Executive Order "stops regulations in their tracks if they were not finalized before January 20, 2017" and cite as a "prime example" the FDA's "proposed 'NNN rule' that would regulate a specific carcinogenic compound in smokeless tobacco products (like snuff and chewing tobacco)." They argue that, under the Executive Order, promulgation of the NNN rule would require the FDA "to swap other public health protections (without regard to the statutorily mandated public health considerations) or find other duly-promulgated rules to eliminate within HHS more broadly."

They also argue that the Executive Order complicates the promulgation of certain rules that are required by the TCA and that are now overdue under the TCA. They cite overdue regulations or guidances required concerning modified risk tobacco products; tobacco product constituents, ingredients, and additives; and color graphics and text warnings for cigarette packaging and advertising. The organizations complain that the Executive Order presents an additional "hurdle" of identifying two regulations to repeal for each such rule. Further, "[t]he FDA could be forced to trade tobacco control for" priorities under other provisions of the Food, Drug & Cosmetic Act.

THE FEDERAL COURTS' STANDING REQUIREMENT

A critical issue in Public Citizen, Inc. v. Trump is the plaintiffs' "standing." Standing is a requirement that the plaintiff has suffered a sufficient injury in fact, which is fairly traceable to the defendant's challenged conduct and which is capable of being redressed by the Court. A generalized policy grievance will not suffice. If the plaintiff lacks standing, the Court lacks jurisdiction to hear or resolve the dispute.

When an organization is a plaintiff, it can seek to establish "organizational standing" in its own right. Alternatively, it could establish "associational standing" if (among other criteria) one of its members would otherwise have standing.

The standing issue has been a significant one in Public Citizen v. Trump. Several different rulings having been issued by the Court so far, and the question remains unresolved.

FIRST AMENDED COMPLAINT DISMISSED FOR LACK OF STANDING

On May 12, 2017, the defendants filed a motion to dismiss the plaintiffs' first amended complaint, arguing a lack of standing. As there were no individual plaintiffs, the plaintiff organizations tried to establish associational standing or, alternatively, standing in their own right as organizations. The Court granted the motion to dismiss on February 26, 2018.

Seeking to establish associational standing, the plaintiffs contended that the Executive Order would prevent or delay "an array of regulatory actions." The prevented or delayed regulatory action, the plaintiffs argued, would harm their members by preventing safety or other measures that might otherwise mitigate the dangers of certain products or services. The Court was not convinced. The main problem was that the plaintiffs failed to plausibly allege that any regulations ostensibly prevented or delayed by the Executive Order would substantially increase the risk of harm to the members or cause the members to face a substantial probability of such harm.

On organizational standing, the plaintiffs argued that the Executive Order has a "chilling effect" on their missions to encourage federal agencies to adopt regulations they advocate. The Court also rejected this argument. The Executive Order did not itself chill any advocacy by the plaintiffs, who would merely have to evaluate the two-for-one tradeoff in deciding how to advocate.

Finding that the plaintiffs lacked standing, the Court dismissed the first amended complaint but allowed the plaintiffs to file another amended complaint seeking to cure the defects in standing.

SECOND AMENDED COMPLAINT WITHSTANDS DISMISSAL; PLAINTIFFS DENIED SUMMARY JUDGMENT ON STANDING

The plaintiffs filed a second amended complaint on April 2, 2018. The defendants again moved to dismiss, challenging the plaintiffs' standing. The plaintiffs also filed a motion for summary judgment to the effect that they had affirmatively established standing. In a decision dated February 8, 2019, the Court denied both motions.

This time, the plaintiffs had alleged standing sufficient to withstand the motion to dismiss. They identified a delayed regulation that plausibly caused some members a sufficient injury based on an inability to purchase and access certain services that would have been required by the regulation. In denying the plaintiffs' motion for summary judgment, however, the

Court determined that their standing remained a subject of genuine dispute for later resolution.

The difference in the Court's rulings stemmed from differing procedural standards. The plaintiffs faced a "far more demanding standard" in seeking to affirmatively establish standing on summary judgment.

CASE STATUS

A federal court cannot reach the merits of a case unless the plaintiff has standing, and standing remains a genuinely-disputed question in the litigation. Following the rulings in connection with the second amended complaint, the Court allowed discovery on the question of standing. Since then, the parties have filed cross-motions for summary judgment on the same question.

Should the Court find that the plaintiffs have standing in this case, it will move toward the merits stages in which the Court will be presented with the question whether the Executive Order, the guidances implementing it, and the federal agencies' adherence to it are lawful. Should it find a lack of standing, it will dismiss the case.

IMPLICATIONS FOR LITIGATION ARISING OUT OF TOBACCO REGULATION

As with the plaintiffs in Public Citizen v. Trump, plaintiffs in other cases have filed challenges to the FDA's regulatory action or inaction concerning tobacco, even though the plaintiffs themselves were not subject to the FDA's regulatory authority under the TCA. And as the Court has acknowledged in Public Citizen v. Trump, "[i]t is relatively easy to establish standing when you are the regulated party; it is more difficult to do so when the government fails to regulate the conduct of someone else."

In cases filed by plaintiffs concerning tobacco regulation "of someone else," the standing decisions have come down on both sides. For instance, in Sproule v. FDA, et al., No. 9:17-cv-80709 (S.D. Fla.), the Count found that an individual plaintiff lacked standing to challenge the FDA's agreement with a tobacco-product manufacturer resolving a modified risk tobacco product issue. In contrast, in American Academy of Pediatrics, et al. v. FDA, et al., No. 8:18-cv-00883 (D. Md.), the Court found that organizational plaintiffs had standing to challenge FDA guidance extending deadlines for tobacco-product manufacturers' submission of premarket tobacco product applications.

Standing decisions are fact-specific and can be difficult. What seems to be clear, however, is that persons not regulated by the federal regulatory decisions they challenge will continue to challenge them. This is particularly true in the tobacco industry, and the ultimate outcome in the challenge to President Trump's "two-for-one" executive order will have implications for both ongoing challenges by third parties to FDA tobacco regulations, as well as the FDA's ability to implement new tobacco regulations. S

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