Supreme Court Won't Hear Latest ENDS Industry Challenges to FDA Regulation

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We previously blogged about two cases challenging the constitutionality of FDA's "Deeming Rule," the authority by which FDA extended its regulation of tobacco products to electronic nicotine delivery systems ("ENDS").

Both of these cases, *Big Time Vapes, Inc. v. FDA* and *Moose Jooce v. FDA* recently hit a dead end when the Supreme Court denied both plaintiffs' petitions for review.

Big Time Vapes sought to overturn the Fifth Circuit's holding that it was not unconstitutional for Congress to delegate to FDA the authority to deem products subject to the Family Smoking Prevention and Tobacco Control Act's ("TCA") regulatory scheme.

Big Time Vapes, Inc. and the United States Vaping Association originally sued FDA contending that the TCA unconstitutionally delegated to the Secretary of Health and Human services the power to deem additional products subject to the TCA's mandates, in violation of Article I, §1 of the United States Constitution, which states "All legislative Powers herein granted shall be vested in a Congress of the United States." Although this Article *is* meant to be a limit on congressional delegation of legislative power, the Fifth Circuit re-articulated the longstanding principle that delegation is constitutional so long as Congress has enumerated, via legislation, a general policy, the agency tasked with enforcement, and the boundaries of the delegated authority.

The Fifth Circuit found that Congress appropriately met all of these standards with the passage of the TCA and section 901's deeming authority. Not only does the TCA articulate clearly stated purposes related to the protection of public health and youth access to nicotine products, it cabins its delegation of authority to FDA by clearly defining tobacco products in Section 101, and outlines regulatory compliance requirements for tobacco manufacturers. Thus, the court found, "Congress painted much of the regulatory canvas, leaving the finishing touches to the FDA."

In *Moose Jooce v. FDA*, most recently heard in the Court of Appeals for the DC Circuit, Plaintiffs challenged the Deeming Rule on the grounds that it violates the Constitution's Appointments Clause and First Amendment.

The Appointments Clause (U.S. Const. Art. II § 2) of the Constitution requires that principal and inferior Officers of the US be appointed by the President, courts, or department heads. The Deeming Rule was promulgated by Leslie Kux, the Associate Commissioner for Policy. Because Kux was not properly appointed as either a principal or inferior officer (i.e., she was not appointed by the President, a court, or the head of a department), plaintiffs claimed the Deeming Rule was promulgated in violation of the Appointments Clause and must be void.

The DC Circuit agreed with FDA that the Rule's ratification by principal officers cured any defects with Kux's promulgation of the Rule. The Rule was first ratified by previous FDA Commissioner Robert Califf, and then ratified a second time Califf's successor, Scott Gottlieb. In fact, Commissioner Gottlieb issued his statement ratifying the Rule *in response* to the questions raised by the *Moose Jooce* case, but the court held that this timing did not nullify the curative effects of his statement.

Plaintiffs' First Amendment claim challenging the modified risk tobacco product premarket authorization pathway also failed based on the DC Circuit's previous holding in *Nicopure Labs v. FDA*, which we wrote about here.

The *Moose Joose v. FDA* petition for review to the Supreme Court won the attention of libertarian think tank The Cato Institute and a small group of Republican senators who filed amici briefs in support of the ENDS plaintiffs and against what they perceive to be an alarming trend of agency regulations promulgated without proper accountability. Nonetheless, the Supreme Court declined to take up the matter, leaving the DC Circuit's approval of the ratification process in place.

The Supreme Court's denial of Big Time Vapes' and Moose Jooce's petitions for review deals a blow to the ENDS industry's attempts to challenge FDA regulation of their products. It appears the industry may be out of luck when it comes to avoiding the lengthy and expensive premarket review process.