IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NICOPURE LABS, LLC and RIGHT TO BE SMOKE-FREE COALITION, *et al.*,	)	
Appellants,	)	
v.	)	Civ. No. 17-5196
FOOD AND DRUG ADMINISTRATION, *et al.*,	)	
Appellees.	)	

APPELLANTS' STATEMENT OF ISSUES

Pursuant to this Court's Order dated September 1, 2017, Appellants in this case hereby submit the following statement of issues to be raised in this proceeding. Appellants have challenged various provisions of the Family Smoking Prevention and Tobacco Control Act ("TCA"), 21 U.S.C. § 387 *et seq.*, as well as the U.S. Food and Drug Administration's ("FDA") final rule which "deems" e-vapor products, including electronic cigarettes and e-liquids used in those devices, to be "tobacco products" under the statute and therefore covered by the TCA's provisions, 81 Fed. Reg. 28,974 (May 10, 2016) ("Deeming Rule"). Appellants reserve the right to amend this statement and to address other issues, including those raised by Appellees.

1. Whether FDA violated the TCA when it deemed particular e-vapor products, including, but not limited to, non-nicotine and non-tobacco containing vaping devices and e-liquids.

2. Whether FDA was required to conduct a cost-benefit analysis before finalizing the Deeming Rule and, if so, whether FDA's purported cost-benefit analysis complied with statutory/regulatory requirements, including, but not limited to, the TCA and Administrative Procedure Act ("APA").

3. Whether FDA violated the APA by deeming e-vapor products, including, but not limited to, applying all PMTA requirements to such products.

4. Whether the TCA and Deeming Rule violate the First Amendment by prohibiting the distribution of free e-vapor product samples.

5. Whether the TCA and Deeming Rule, through the Modified Risk Tobacco Product ("MRTP") process, violate the First Amendment by regulating truthful, non-misleading statements about e-vapor products, including, but not limited to, statements that a given product contains reduced levels of, or presents reduced exposures to, a substance or is entirely free of a substance.

6. Whether FDA's failure to consider an adequate Pre-Market Tobacco Application ("PMTA") compliance period for e-vapor manufacturers violated the Regulatory Flexibility Act and APA.

7. Whether FDA violated the TCA and APA by not establishing a new Grandfather Date for e-vapor products or, in the alternative, whether the TCA violates the U.S. Constitution's Substantive Due Process Clause in the event that the statute does not permit FDA to establish a new Grandfather Date.

Dated: October 2, 2017

/s/ *Eric P. Gotting*

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CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of October, 2017, I electronically filed the foregoing document with the Court by using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

/s/ *Eric P. Gotting*
Eric P. Gotting