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VAPE WARS: THE DEEMING RULE AND CHEVRON REFERENCE

U.S. Department of Health and Human Services
Food and Drug Administration

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The Food and Drug Administration (hereinafter referred to as FDA) recently expanded its authority to regulate electronic cigarettes.[i]
(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_edn1) In an attempt keep the e-cigarette and e-liquid industry relatively unregulated, three companies that make liquids for have recently filed a suit in the U.S. District Court for the Middle District of Alabama. [ii]
(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_edn2)

Their complaint argues against the "deeming rule" which allows the FDA to "deem all products that meet the definition of tobacco product under the law..."[iii]
(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_edn3) The stated purpose for this expansion is to protect the general health of the public. [iv]
(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_edn4) The companies' complaint argues that the this rule expanded FDA authority beyond the statutory limits of the Tobacco Control Act, a statute that granted the FDA broad regulatory authority of the distribution of tobacco products. [v]
(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_edn5) Further, the plaintiffs indicatedpointed out that the stated purpose of the statute was to address serious adverse health effects associated with tobacco products. [vi]
(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_edn6)





The plaintiffs contend that the FDA acted in an arbitrary and capricious manner because: (i) the agency relied on factors which Congress had not intended the FDA to consider, such as the emergence of e-cigarettes; (ii) the FDA did not offer an explanation for its decision, which ran counter to the evidence before the FDA; or (iii) because the decision was so implausible that it could not be ascribed to a difference in view or the product of FDA expertise. [vii]

(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_edn7) Finally, the plaintiffs also argue that having their products screened before the products hit the market would be too expensive and wipe them off the market. [viii]
(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_edn8)

In 2010, a different group of e-cigarette companies attempted to halt the FDA's power to regulate their products. [ix]

(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_edn9) In that case, the court applied *Chevron* deference because the FDA's interpretation and application of the relevant statutory provisions formed the basis of its decision to refuse the entry of the products. [x]

(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_edn10) Even so, that decision stated that such a reading of the statute was neither a reasonable construction nor application of those provisions that spoke about tobacco products. [xi]

(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_edn11)

As Congress has yet to decide the fate of the electronic cigarette industry, it is becoming increasingly clear that there will be more litigation about the FDA's authority to regulate the industry. However, it should be noted that *Chevron* deference will likely apply in all of those cases and the manner in which a specific circuit has treated that deference will probably be outcome determinative in most instances.

[i]
(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_ednref1) Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, No. FDA-2014-N-0189, 81 Fed. Reg. 28, 973 (May 10, 2016) (to be codified at 21 CFR Parts 1100, 1140, and 1143). available at <https://www.gpo.gov/fdsys/pkg/FR-2016-05-10/pdf/2016-10685.pdf>.

[ii]
(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_ednref2) Martina Barash, *Another Suit Filed to Stop Tobacco Rule Affecting E-cigs*, *Toxics Law Reporter* (Jul. 14, 2016), available at <http://news.bna.com.ezproxy.law.uky.edu/>

rxln/TXLNWB/split_display.adp?fedfid=93990901&cvname=trnotallissues&fa=93990901&jd=93990901.

[iii]
(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_ednref3) Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, *Deeming*, 81 Fed. Reg. *supra* note 2, at 28975.

[iv]

(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_ednref4) *Id.*

[v]

(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_ednref5) Complaint at 5, *Cyclops Vapor 2, LLC v. U.S. Food & Drug Admin. FDA*, M.D. Ala., No. 2:16-cv-00556, 5, , complaint filed (M.D. Ala. 2016) Jul. 8, 2016 *available at* [https://www.bloomberglaw.com/public/desktop/document/](https://www.bloomberglaw.com/public/desktop/document/Cyclops_Vapor_2_LLC_et_al_v_United_States_Food_and_Drug_Administr?1470016543)

[Cyclops_Vapor_2_LLC_et_al_v_United_States_Food_and_Drug_Administr?1470016543](https://www.bloomberglaw.com/public/desktop/document/Cyclops_Vapor_2_LLC_et_al_v_United_States_Food_and_Drug_Administr?1470016543).

[vi]

(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_ednref6) *Id.*

[vii]

(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_ednref7) *Id.* at 9 (citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

[viii]

(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_ednref8) Barash, *supra* note 3.

[ix]

(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_ednref9) *Smoking Everywhere, Inc. v. U.S. Food & Drug Admin.*, 680 F. Supp 62, 68 (D.C. 2010).

[x]

(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_ednref10) *Id.*

[xi]

(file:///C:/Users/Evan/Documents/KJournal/Online%20Editor%20Stuff/Blog%20Posts/vapeblogpost-2.docx#_ednref11) *Id.* at 69.

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