ORAL ARGUMENT NOT YET SCHEDULED
No. 16-1128

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

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COMPETITIVE ENTERPRISE INSTITUTE,
THE CONSUMER ADVOCATES FOR SMOKE-FREE ALTERNATIVES ASSOCIATION, and GORDON CUMMINGS,

Petitioners,

v.

UNITED STATES DEPARTMENT OF TRANSPORTATION, and ANTHONY FOXX, in his official capacity as Secretary of the U.S. Department of Transportation,

Respondents.

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On Petition for Review of an
Order of the Department of Transportation

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# FINAL OPENING BRIEF OF PETITIONERS

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## CERTIFICATE OF PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rules 12(c) and 28(a)(1), Petitioners submit this provisional certificate as to parties and related matters:

Parties and *Amici* – This case involves the following parties:

Petitioners: Competitive Enterprise Institute; The Consumer Advocates for Smoke-Free Alternatives Association ("CASAA"); and Gordon Cummings.

Respondents: The respondents are the United States Department of Transportation, and Anthony Foxx, in his official capacity at Secretary of the United States Department of Transportation.

Intervenors: The Court has not granted any motions to intervene at this time, nor have any motions been filed.

Amici: The Court has not granted any motions to participate in this case as amicus curiae, nor have any motions been filed.

The Competitive Enterprise Institute is a non-profit 501(c)(3) corporation organized under the law of the District of Columbia for the purpose of defending free enterprise, limited government, and the rule of law. It has no parent companies. No publicly-held corporation has a 10% or greater ownership interest in it, or indeed, any interest in it at all. CASAA is a non-profit 501(c)(4) organization incorporated in Alabama that works to protect its members' and the

public's right to access reduced harm alternatives to smoking, such as e-cigarettes. CASAA has over 120,000 registered members, including thousands of e-cigarette users. It has no shareholders and no parent companies, and no corporation has any ownership interest in it.

Rulings Under Review – This is a challenge to a final rule of the United States Department of Transportation entitled *Use of Electronic Cigarettes on Aircraft,* published at 81 Fed. Reg. 11,415 (Mar. 4, 2016).

Related Cases – There are no related cases, and this case has not been previously before this court. Nor have there been any district court proceedings.

Respectfully submitted,

_____/s/_____
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## RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure Rule 26.1 and Circuit Rule 26.1, Petitioners make the following disclosures: Competitive Enterprise Institute is a non-profit 501(c)(3) corporation organized under the laws of the District of Columbia for the purpose of defending free enterprise, limited government, and the rule of law. It has no parent companies. No publicly-held corporation has a 10% or greater ownership interest in it.

The Consumer Advocates for Smoke-free Alternatives Association (CASAA) is a non-profit organization incorporated in Alabama. It has IRS non-profit 501(c)(4) status. Founded in 2009, it works to protect its members' and the public's right to access reduced harm alternatives to smoking, such as e-cigarettes. CASAA has over 120,000 registered members, including thousands of users of e-cigarettes. It has no shareholders and no parent companies, and no corporation has any ownership interest in it.

## STATEMENT REGARDING DEFERRED APPENDIX

The parties have conferred and intend to use a deferred joint appendix.

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## GLOSSARY

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|---|---|
| ADA | Airline Deregulation Act |
| APA | Administrative Procedure Act |
| CASAA | Consumer Advocates for Smoke-Free Alternatives Association |
| CEI | Competitive Enterprise Institute |
| DOT | United States Department of Transportation |
| FAA | Federal Aviation Administration |
| JA | Joint Appendix |
| NPRM | Notice of Proposed Rulemaking |
| ppb | Parts per billion |
| ppm | Parts per million |

## JURISDICTIONAL STATEMENT

The Petition for Review is authorized by 49 U.S.C. § 46110(a) and 5 U.S.C. § 702, because it is a challenge to final agency action by the Department of Transportation, and was timely filed by Petitioners on April 28, 2016. It challenges DOT's final rule, "Use of Electronic Cigarettes on Aircraft," 81 Fed. Reg. 11415 (March 4, 2016), JA384.

## STATEMENT OF ISSUES

1. Whether DOT acted in accordance with law in banning the use of electronic cigarettes (e-cigarettes) on airplanes on the basis of the prohibition on smoking contained in 49 U.S.C. § 41706;

2. Whether DOT acted arbitrarily and capriciously in banning the on-board use of e-cigarettes on the basis of air carriers' duty to "provide safe and adequate interstate air transportation" under 49 U.S.C. § 41702, given, among other reasons, the lack of evidence that e-cigarettes pose a significant risk to airline passengers, DOT's failure to adequately present the evidence for its conclusion during the rulemaking, and its reliance on studies published after the close of the comment period;

3. Whether DOT acted arbitrarily and capriciously in banning the on-board use of e-cigarettes as an "unfair or deceptive practice in air transportation"

under 49 U.S.C. § 41712, given, among other reasons, that such use is neither deceptive nor fraudulent.

## STATUTES AND REGULATIONS

The Statutory Addendum contains pertinent statutes and regulations.

## STATEMENT OF THE CASE

In 2011, the Department of Transportation issued a Notice of Proposed Rulemaking, soliciting comment on its proposal to ban the use of electronic cigarettes by airline passengers, with a comment deadline of November 14, 2011. *See* Smoking of Electronic Cigarettes on Aircraft, 76 Fed. Reg. 57008 (Sept. 15, 2011) [JA178]. DOT cited the statute banning smoking on aircraft, 49 U.S.C. § 41706 "as the statutory authority for this NPRM." *Id.* at 57009 [JA179]. But it also cited a second statute, 49 U.S.C. § 41702, which mandates that an "air carrier shall provide safe and adequate interstate air transportation," as an additional source of potential authority. *Id.* DOT relied on the statute banning smoking even though it noted that "a vapor, rather than smoke, is produced" by e-cigarettes. *Id.*

In response to the NPRM, petitioners CASAA and CEI submitted comments arguing that banning e-cigarettes would actually increase transportation-related deaths by driving nicotine-dependent passengers to drive rather than fly, and would undermine rather than promote passenger comfort by subjecting passengers to nicotine withdrawal symptoms that are a common cause of "air rage." They

argued there are "clear benefits of permitting the in-flight use of e-cigarettes." First, research shows that "e-cigarettes can alleviate the tobacco withdrawal symptoms faced by smokers on flights."[1] According to one travel website, "'it has recently been recognized that a common cause of air rage is nicotine withdrawal in heavy smokers on long-distance "no smoking" flights.'"[2]

Moreover, petitioners argued, "the growing popularity of e-cigarettes indicates that many smokers prefer them to other non-combustion nicotine delivery systems. Allowing their in-flight use would make many smokers far more comfortable on flights." "Secondly, many smokers do not fly precisely because they find the prospect of flying uncomfortable due to their inability to smoke on those flights (which may well involve long airport waits and connecting flights as well)."[3]

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[1] Comments of CASAA and CEI (Nov. 14, 2011), 1st attachment, at pg. 4, JA220 (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0689), *citing* Andrea R. Vansickel at al., *A Clinical Laboratory Model for Evaluating the Acute Effects of Electronic "Cigarettes": Nicotine Delivery Profile and Cardiovascular and Subjective Effects*, American Association for Cancer Research Journal (July 20, 2010), at 7 ("the two products tested in this study produced some tobacco abstinence symptom suppression … In spite of delivering no measurable nicotine, both electronic cigarettes tested in this study reduced ratings of 'craving a cigarette' and 'urge to smoke'"), JA304.

[2] Comments of CASAA and CEI at pg. 4, JA220 (citing The Travel Doctor, http://www.traveldoctor.co.uk/flights.htm).

[3] Comments of CASAA & CEI at 4, JA220 (citing *Smokers: No Butts, It's A Drag Smokers Are Coping With No-smoking Bans On Some Domestic Flights: They Drive, Schedule Layovers Or Stay Home*, Orlando Sentinel, Feb. 7, 1993,

Thus, their comments argued, banning e-cigarettes could result in increased mortality: "The possibility of inflight e-cigarette use may well induce them to fly when they otherwise would have driven. Given that commercial flights are far safer than driving, especially over long distances, this increase in flying by such smokers could well save lives. (On the basis of deaths per passenger mile travelled, air travel is at nearly 200 times safer than car travel…)."[4]

Petitioners also submitted studies concluding that electronic cigarettes did not pose the sort of health risk associated with cigarettes, and indeed, had not harmed any user's health. *See, e.g.*, Zachary Cahn & Michael Siegel, *Electronic Cigarettes as a Harm Reduction Strategy for Tobacco Control: a Step Forward or a Repeat of Past Mistakes?* 2010 Journal of Public Health Policy 1-16, at 11 ("none of the more than 10,000 chemicals present in tobacco smoke, including over 40 known carcinogens, has been shown to be present in the cartridges or vapor of electronic cigarettes in anything greater than trace quantities. No one has reported adverse effects, although this product has been on the market for more than 35 years"; the minute "levels of these carcinogens was similar to that in NRT products" that the FDA authorizes as safe).

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http://articles.orlandosentinel.com/1993-02-07/travel/9302030027_1_smoking-layover-airport).

[4] *Id.* at 4, JA220 (citing http://www.airlinereporter.com/2010/09/flying-is-safe-and-i-am-going-to-prove-it/).

After 4 ½ years of inactivity, DOT issued its final rule banning the use of electronic cigarettes by airline passengers. *Use of Electronic Cigarettes on Aircraft*, 81 Fed. Reg. 11415 (Mar. 4, 2016). This time, it relied not only on the two statutes cited in the NPRM (49 U.S.C. §§ 41702 and 41706), but also a different statute it had not previously mentioned in the NPRM (49 U.S.C. § 41712), banning an "air carrier" from "engag[ing] in an unfair or deceptive practice . . . in air transportation." 81 Fed. Reg. at 11421 [JA390].

DOT first defined the use of e-cigarettes as "smoking," in violation of 49 U.S.C. § 41706, which provides that an "individual may not smoke" in "an aircraft" in interstate or intrastate air transportation. 81 Fed. Reg. at 11419–20 [JA388-89]. DOT recognized that "e-cigarettes are 'vaped' and produce a vapor" and "do not undergo combustion" the way that "traditional cigarettes" do. *Id.* at 11420 [JA389]. But it interpreted its authority to "implement the statutory smoking ban" as giving it the authority both to "define the term 'smoking,' and to refine that definition as necessary to effectuate the purpose of the statute." *Id.* at 11419.

DOT then defined smoking to include e-cigarettes. It stated that e-cigarettes are "generally designed to look like and be used in the same manner as conventional cigarettes," and the fact that their vapor, like smoke, "introduces a cloud of chemicals into the air that may be harmful to passengers," which it concluded was at odds with the "purpose behind the statutory ban on smoking . . .

to improve cabin air quality, reduce the risk of adverse health effects," and "enhance passenger comfort." *Id.* at 11420 [JA389].

It conceded that "some studies have found that lower levels of toxicants are observed in e-cigarette aerosols than in combusted tobacco smoke," and that "the specific hazards of e-cigarette aerosol have not yet been fully identified." *Id.* at 11420 & n.12 [JA389]. But it declined to "exempt" e-cigarettes from the ban, citing seven studies discussing how e-cigarette aerosols allegedly "contain harmful substances or respiratory irritants." *Id.* at 11420 & nn.7–13 [JA389]. None of these studies were mentioned in the NPRM, and six postdated the close of the comment period. It then declined to "exempt" e-cigarettes from the ban, although it noted that "the specific hazards of e-cigarette aerosol have not yet been fully identified." *Id.* at 11420 [JA389].

DOT next asserted its authority to ban e-cigarettes under 49 U.S.C. § 41702, which mandates "safe and adequate service." It suggested that it had the authority to do so to ensure "adequate" service, even if e-cigarette vapor "did not represent a health hazard to nonsmoking passengers on aircraft," 81 Fed. Reg. at 11420 [JA389], as long as it produced a level of "passenger discomfort" "similar" to that engendered by secondhand tobacco smoke. *Id.* at 11421 [JA390]. "First, the non-user passenger may feel the direct effects of inhaling the aerosol, which, as noted above, has been shown to contain respiratory irritants. More broadly, passengers

may reasonably be concerned that they are inhaling unknown quantities of harmful chemicals." *Id.*

Later, in discussing the perceived benefits and costs of its rule, DOT noted that the "adverse health consequences associated with secondhand exposure to tobacco smoke are well-documented," and raised the possibility that "e-cigarettes may also have adverse health impacts." *Id.* at 11426 [JA395]. Although DOT relied on a "passenger comfort" rationale, it only vaguely alluded to petitioners' argument that banning e-cigarettes would actually harm passenger comfort by inflicting nicotine withdrawal symptoms on e-cigarette users. *Id.* at 11425 [JA394]. Nor did it address petitioners' argument that banning e-cigarettes would increase mortality by inducing e-cigarette users to travel more hazardously by car rather than more safely by airplane.

## SUMMARY OF ARGUMENT

DOT improperly banned the use of e-cigarettes under the anti-smoking statute, 49 U.S.C. § 41706, because e-cigarettes do not burn (or even contain) tobacco, much less produce smoke. DOT's reliance on the anti-smoking statute to ban e-cigarettes violates the plain language of the statute, conflicts with its concession that e-cigarettes produce "a vapor, not smoke," and contradicts its past recognition that this statute imposes only "a ban on smoking of tobacco products."

DOT acted arbitrarily and without proper notice in banning e-cigarettes under 49 U.S.C. § 41702, which requires air carriers "to provide safe and adequate service, equipment and facilities." It did not give proper notice of the seven studies it relied upon in its final rule. None of those seven studies had been cited in DOT's NPRM, and six were released after the close of the deadline for comment. Moreover, none of those studies show that e-cigarettes actually interfere with passenger comfort, or health and safety. Instead, they merely found trace amounts of certain chemicals in e-cigarette vapor, or on surfaces exposed to such vapor. Those chemicals are found in commonly-used products or foods permitted on flights, and could only cause harm at much higher doses. The levels found in e-cigarette vapor are trivial in comparison to pre-existing air cabin contaminant levels.

DOT did not respond to evaluate the studies submitted by commenters showing that e-cigarettes cause no harm. DOT also simply ignored petitioners' arguments about the passenger comfort and health and safety benefits of *allowing* e-cigarettes, which reduces air rage, withdrawal symptoms, and road-related mortality. Moreover, DOT relied on speculation about putative harms, rather than addressing a demonstrated problem. And even if some passenger discomfort or health risk actually had been shown, DOT lacked the power to ban insignificant

risks or impediments to passenger comfort – as precedent construing similar "safe" and "adequate" language in other statutes shows.

DOT also wrongly relied on the statute banning an "air carrier" from "engag[ing] in an unfair or deceptive practice . . . in air transportation," 49 U.S.C. § 41712, to ban e-cigarettes. First, DOT never even mentioned it in the Notice of Proposed Rulemaking, providing no notice to the public that it might rely upon it. Moreover, this statute only applies to airline conduct, not passenger conduct like e-cigarette use, and it does not reach non-misleading activity such as e-cigarette use. Nor does it allow an agency to regulate based on speculative harms.

## STANDING

As an e-cigarette user who regularly travels by airplane, petitioner Gordon Cummings has standing to challenge DOT's rule. *State National Bank v. Lew*, 795 F.3d 48, 55 (D.C. Cir. 2015) ("a regulated individual or entity has standing to challenge an allegedly illegal statute or rule under which it is regulated.'") (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992)). Cummings is directly regulated, since individual violators of the rule can be fined a substantial civil penalty, or face a criminal fine of up to $5,000.[5] *See also* Final Rule, 81 Fed. Reg. at 11418; 49 U.S.C. § 46301; 14 C.F.R. § 383.2(a); 14 C.F.R. § 121.317(g).

[5] Under two of the statutes pursuant to which DOT imposed the e-cigarette ban—49 U.S.C. §§ 41702 and 41706—"an individual" who violates either section is liable "for a civil penalty of not more than…$1,100." 49 U.S.C. 46301(a)(1)(A).

As an association of e-cigarette users, petitioner CASAA has associational standing to challenge bans on e-cigarette use. *N.Y.C.L.A.S.H. v. New York*, 315 F. Supp. 2d 461, 468–70 (S.D.N.Y. 2004) (association of smokers had associational standing to bring challenges to smoking bans). Petitioners CASAA and CEI, which participated in the rulemaking below by submitting comments, also have standing to challenge such bans on behalf of their board members and employees who use E-cigarettes, such as CEI staffer Cummings. *Hang-On, Inc. v. Arlington*, 65 F.3d 1248 (5th Cir. 1995). Further explanation of petitioners' basis for standing is found in the attachment to their docketing statement, and the declarations of Julia Woessner, Gordon Cummings, and Elaine Keller attached hereto in the Addendum on Standing. As these declarations show, DOT's new rule has adversely affected Mr. Cummings and Ms. Keller personally, and CASAA members as well.

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Section 41706 provides that an "individual may not smoke…" DOT regulations also are aimed at individual smokers. *E.g.,* 14 C.F.R. § 121.317(g) ("no person may smoke…"). The maximum civil penalty is higher under the third statute, 49 U.S.C. § 41712. *See* 49 U.S.C. § 46301(a)(5)(D) (setting $2,500 penalty); *Revisions to Denied Boarding Compensation, Domestic Baggage Liability Limits, and Civil Penalty Amounts*, 80 Fed. Reg. 30144, 30145 (2015) (amending 14 C.F.R. § 383.2(b)(3)) (increasing that penalty by 10%).

Regarding criminal penalties, "a person that knowingly and willfully violates … a regulation prescribed … by the Secretary of Transportation … under [this subtitle] … shall be fined under title 18." 49 U.S.C. § 46316(a). A criminal offense for which "no imprisonment is authorized" is considered an "infraction." 18 U.S.C. § 3559(a)(9). For an infraction that does not specify the maximum fine, an individual violator may not be fined more than $5,000. 18 U.S.C. § 3571(b)(7).

## STANDARD OF REVIEW

A reviewing court may set aside an agency determination pursuant to 5 U.S.C. § 706(2) if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction," "without observance of procedure required by law" or "unsupported by substantial evidence." Although this Court may not simply "substitute its judgment" for the agency's, its review must "be searching and careful." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). An "agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983).

## ARGUMENT

### I. Because E-Cigarettes Do Not Burn Tobacco, DOT Cannot Ban Them Under the Anti-Smoking Statute, 49 U.S.C. § 41706

The first of the three statutes DOT invoked to impose its ban on electronic cigarettes was 49 U.S.C. § 41706, which provides that: "An individual may not smoke" in "an aircraft" in interstate or intrastate air transportation. As is shown below, this statute does not cover electronic cigarettes. It applies to the burning of tobacco products. E-cigarettes, on the other hand, do not involve combustion at all, and they produce vapor, not smoke. *See People v. Thomas*, 24 N.Y.S.3d 884, 891

(N.Y. Sup. Ct. 2016) ("An electronic cigarette neither burns nor contains tobacco," and thus does not violate laws against "smoking").

The non-smoking nature of e-cigarettes was expressly recognized by DOT. It stated that they produce "a vapor, rather than smoke." NPRM, 76 Fed. Reg. at 57009 [JA179]; *see also* Final Rule, 81 Fed. Reg. at 11424 ("e-cigarettes" produce "aerosol which can be mistaken for smoke") [JA393]. And it distinguished e-cigarettes from "combusted tobacco products." *Id.* [JA389]

By contrast, the statutory ban on smoking, codified in 1994, used the term "smoke" in its conventional sense: to "breathe smoke into the mouth or lungs from burning tobacco." Cambridge English Dictionary, *Smoke*, http://dictionary.cambridge.org/us/dictionary/english/smoke.[6] DOT accepted this conventional meaning when it originally implemented the statute in 14 C.F.R. § 252.1 (1-1-01 Edition).[7] In its words, "a ban on smoking of tobacco products" is what is "required by 49 USC 41706." *Id.*

But DOT now claims that it has the authority to redefine the term smoking. It claims the power to "define the term 'smoking,' and to refine that definition as

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[6] *See Perrin v. United States,* 444 U.S. 37, 42 (1979) ("unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning.").

[7] Available at https://www.gpo.gov/fdsys/pkg/CFR-2001-title14-vol4/pdf/CFR-2001-title14-vol4-part252.pdf.

necessary to effectuate the purpose of the statute . . . . to improve cabin air quality, reduce the risk of adverse health effects," and "enhance passenger comfort." *Id.* at 11419 [JA388]. An agency cannot, however, redefine a law's plain terms just because that would supposedly promote a statutory purpose. *Board of Governors v. Dimension Financial Corp.,* 474 U.S. 361, 374 (1986) (rejecting "invocation of the 'plain purpose' of legislation at the expense of the terms of the statute"). Agency interpretation "may not be used to overturn the plain language of a statute." *C.I.R. v. Schleier*, 515 U.S. 323, 336 n.8 (1995). "[N]o deference is due to agency interpretations at odds with the plain language of the statute itself." *Public Employees Retirement System v. Betts*, 492 U.S. 158, 171 (1989).

DOT cannot alter the plain meaning of smoking, which simply does not reach smokeless devices such as e-cigarettes. *See Thomas*, 24 N.Y.S.3d at 891; Op. Va. Att'y Gen. (Apr. 27, 2010) ("using an e-cigarette does not fall within the definition of 'smoke' or 'smoking'" in laws banning smoking)[8]; Ariz. Atty. Gen. Opinion I14-004 (R14-012), *Whether Certain Statutes Apply to Electronic Cigarettes* (July 30, 2014), https://www.azag.gov/sgo-opinions/whether-certain-statutes-apply-electronic-cigarettes (smoking ban applies "only to the burning of a tobacco product, which results in smoke," not to "an electronic cigarette"); Kan. Atty. Gen.

[8] *See also* Comment of Kenneth T. Cuccinelli, II (attaching this opinion), JA378-80 (Docket No. DOT-OST-2011-0044, comment ID: DOT-OST-2011-0044-0728 (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0728).

Opinion No. 2011-015 (Oct. 31, 2011) ("using an electronic cigarette . . . is not 'smoking,'" due to absence of "burning") (http://ksag.washburnlaw.edu/opinions/2011/2011-015.pdf).

As petitioners CEI and CASAA noted in their comments, DOT's attempt to redefine the use of electronic cigarettes as "smoking" is at odds not only with the dictionary definition of "smoke," but with this Court's decision in *Sottera Inc. v. FDA*, 627 F.3d 891, 893 (D.C. Cir. 2010), which noted that electronic cigarettes emit "nicotine vapor *without fire, smoke*, ash, or carbon monoxide" (emphasis added).

## II. E-Cigarettes Do Not Interfere With "Safe and Adequate Service" Under 49 U.S.C. § 41702

DOT's second statutory basis is 49 U.S.C. § 41702. It requires air carriers "to provide safe and adequate service, equipment and facilities." But such language does not give boundless powers to administrative agencies to regulate the conduct of businesses, much less their customers, such as airline passengers. This Court and the Supreme Court have consistently interpreted such "safe" and "adequate" language in health and safety statutes to allow agencies to ban only "significant" health risks, not to create "risk-free" environments. *Industrial Union Dept., AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 642 (1980) (plurality opinion) (under workplace safety statute OSHA, neither "safe" nor "adequately safe" allow ban on minor risks like "breathing [smog-filled] city air" or "driving a car";

research indicating two deaths every six years was insufficient to justify regulation, and giving agency a more "open-ended grant" of authority would raise constitutional questions); *Carstens v. NRC*, 742 F.2d 1546, 1557 (D.C. Cir. 1984) (NRC's "statutory mandate to 'provide adequate protection to the health and safety of the public'" required "not a risk-free environment, but a 'reasonable assurance ... that the reactor could be safely operated at the proposed location.'"). Thus, DOT can ban customers from using electronic cigarettes only if they pose significant health risks, or significantly interfere with passenger comfort.

Here, DOT has not shown either of these. As shown below (pp. 25-38), the studies it cites merely indicate the presence in e-cigarette vapor of trace amounts of chemicals—chemicals also found in common foods and household items—that would be harmful (or affect passenger comfort) only in much larger doses. The studies DOT cites do not allege e-cigarette vapor would actually cause discomfort, or that exposure to those chemicals would actually cause harm at the levels actually present in e-cigarette vapor. They certainly do not show a significant health risk. Even if they did, DOT's reliance on those studies would be improper, since they were not subject to comment.

DOT appeared to recognize that its rule cannot be sustained based on safety and health, as opposed to passenger comfort: DOT's rule "relied on the adequate [service] prong" of the statute, rather than its mandate of "safe" service, and DOT

imposed its ban in the name of "passenger comfort." 81 Fed. Reg. at 11421 [JA390]. But the studies DOT cited do not even show any actual (much less significant) impact on passenger comfort from electronic cigarettes.

Nor does DOT show anything analogous to the levels of passenger discomfort associated with secondhand tobacco smoke. As it concedes, even in the early 1970's "a significant portion of the nonsmokers stated that they were bothered by tobacco smoke." *Id.* at 11420 [JA389]. Nothing in the record shows similar discomfort about e-cigarettes. Indeed, the agency does not cite to a single example of passenger irritation during the actual use of an e-cigarette.

As we explain below,[9] what little vapor e-cigarette users exhale quickly dissipates, rather than producing the fog of smoke associated with tobacco cigarettes. E-cigarette vapor becomes invisible within a few seconds, and most forms of e-cigarettes are not detectable by smell. Moreover, e-cigarette vapor released into an air cabin is limited to what a user exhales (most chemicals are absorbed by the users), since an e-cigarette does not emit side-stream "smoke," as DOT's own studies recognize. The chemicals found in e-cigarettes are not harmful at the trace levels in which they are present in e-cigarettes, and they are found in commonly-consumed foods and household products. They are not remotely similar to tobacco cigarettes in terms of their health effects.

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[9] *See infra*, pp. 24-25, 43.

To the extent that people oppose e-cigarettes, it seems to be based in large part on their confusion of e-cigarettes with tobacco cigarettes, rather than their having experienced any actual discomfort due to exposure to e-cigarette vapor. DOT relies on that very confusion to justify banning e-cigarettes, speculating that passengers may "experience discomfort" because e-cigarettes produce "aerosol which can be mistaken for smoke," and "[p]assengers who do not … understand the process of e-cigarette use can easily mistake the act for traditional smoking." 81 Fed. Reg. at 11424 [JA393]. As it put it, "allowing use of e-cigarettes" "would be potentially harmful to passengers" because of "harms" that "include" "confusion about whether the passenger is being exposed to traditional cigarette smoke." *Id.* at 11421 [JA390]. Such mistaken fears are not a rational reason to ban something. *Cf. Cleburne v. Cleburne Living Center*, 473 U.S. 432, 448–50 (1985) (irrational fear is not a valid basis for regulation).

### A. DOT Improperly Relied Upon Studies Published After the Close of the Comment Period

In its final rule, DOT relied exclusively on seven studies that the public was not notified about in the NPRM. [10] In fact, six of the studies were not even in

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[10] 81 Fed. Reg. at 11420 nn.7–13 [JA389] (citing Jan Czogala et al., *Secondhand Exposure to Vapors From Electronic Cigarettes,* 16 Nicotine & Tobacco Research 655 (2014); M.L. Goniewicz & L. Lee, *Electronic Cigarettes Are a Source of Thirdhand Exposure to Nicotine,* Nicotine Tob. Res. 2014 Aug 30; W.G. Kuschner et al., *Electronic Cigarettes and Thirdhand Tobacco Smoke: Two Emerging Health Care Challenges for the Primary Care Provider,* 4 Int J Gen

existence until after the close of the comment period.[11] (Given its 4 ½ year delay in issuing the final rule, perhaps DOT was waiting in vain for a study that would actually provide meaningful support for its rule.)

This was improper, and prevented petitioners and other commenters from analyzing and commenting on those studies. *See Chamber of Commerce v. SEC*, 443 F.3d 890, 900–01 (D.C. Cir. 2006) (An agency cannot rely "on materials not made subject to public comment under section 553(c)," even if "the materials were 'publicly available'"; "The question is whether 'at least the most critical factual material that is used to support the agency's position on review ... [has] been made public in the proceeding and exposed to refutation.'").[12]

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Med. 115 (2011); M.L. Goniewicz, J. Knysak, M. Gawron et al., *Levels of Selected Carcinogens and Toxicants in Vapour From Electronic Cigarettes,* 23 Tobacco Control 133 (2013); Williams, M., A. Villarreal, K. Bozhilov, et al., *Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol,* 8 Public Library of Science One e57987 (2013); Schober, W., et al., *Use of Electronic Cigarettes (E-Cigarettes) Impairs Indoor Air Quality and Increases FeNO Levels of E-Cigarette Consumers,* 217 Int. J. Hyg. Environ. Health 628 (2014); T. Schripp, D. Markewitz, E. Uhde & T. Salthammer, *Does E-Cigarette Consumption Cause Passive Vaping?,* 23 Indoor Air 25 (2013).

[11] The only one of these seven in existence then was W.G. Kuschner et al., *Electronic Cigarettes and Thirdhand Tobacco Smoke: Two Emerging Health Care Challenges for the Primary Care Provider,* 4 Int J Gen Med. 115 (2011), doi: 10.2147/IJGM.S16908.

[12] *See also Am. Radio Relay League, Inc. v. FCC,* 524 F.3d 227, 237 (D.C. Cir. 2008) ("it would appear to be a fairly obvious proposition that studies upon which an agency relies in promulgating a rule must be made available during the rulemaking in order to afford interested persons meaningful notice and an opportunity for comment.").

DOT did cite two studies in its NPRM,[13] as well as two other articles describing those studies[14]; but these studies and articles were not relied upon, or even cited, in DOT's final rule. In short, none of the factual basis for DOT's claim of potential harm was ever subjected to public comment.

### B. DOT's Studies Do Not Even Show Harm to Passenger Comfort or Safety From E-Cigarettes, Which Cause Less Harm Than Other Items It Permits, and Have Little Impact on Pre-Existing Air Cabin Pollutant Levels

None of the studies cited by DOT in either its NPRM or in the final rule conclude that secondhand exposure to e-cigarette vapor is harmful to human health. Nor do they even show that the presence of e-cigarette vapor in aircraft cabins would interfere with passenger comfort. Moreover, some of the studies were irrelevant because they measured the content of the vapor that users inhale, rather than what they exhale (e-cigarettes, unlike tobacco cigarettes, do not produce "sidestream" smoke).

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[13] 76 Fed. Reg. at 57010 [JA180], *citing* G. Wieslander et al., *Experimental Exposure to Propylene Glycol Mist in Aviation Emergency Training: Acute Ocular and Respiratory Effects*, Occupational and Environmental Medicine (2001); 58:649–655; Anna Trtchounian & Prue Talbot, "Electronic nicotine delivery systems: Is there a need for regulation?" *Tobacco Control,* December 7, 2010.

[14] 76 Fed. Reg. at 57010, *citing* ScienceDaily.com, *Electronic Cigarettes are Unsafe and Pose Health Risks, Study Finds*, Dec. 5, 2010 (discussing the Trtchounian study), *New England Journal of Medicine*, "E-Cigarette or Drug-Delivery Device? Regulating Novel Nicotine Products," 365;3: 193–95.

To the extent that some of the studies suggest that secondhand or thirdhand to exposure e-cigarette vapor *might* cause harm or irritation, such claims are entirely speculative, as none of the studies even purport to explore whether e-cigarette vapor contains any substances at a concentration sufficient to affect individuals who experience secondhand or thirdhand exposure.

For example, the final rule claims "[a] recent study published in the journal Nicotine & Tobacco Research found that e-cigarettes are a source of secondhand exposure to nicotine but not to combustion toxicants." 81 Fed. Reg. at 11420 & n.7 [JA389]. But this study, Czogala *et al.*, explained that it "did not test potential health effects associated with secondhand exposure to vapors from e-cigarettes."[15] Instead, it merely found that "that e-cigarettes *might* involuntarily expose nonsmokers and people who do not use e-cigarettes to nicotine," and that e-cigarettes might expose bystanders to "low levels of nicotine but *not* to the other toxins found in tobacco smoke."[16] The study added a caveat to this finding, noting that "[i]t remains unclear whether exposure to low levels of nicotine indoors causes any harm to bystanders."[17] Moreover, it observed that "the emissions of nicotine

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[15] Jan Czogala et al., *Secondhand Exposure to Vapors From Electronic Cigarettes,* 16 Nicotine & Tobacco Research 655, 661 (2014), doi: 10.1093/ntr/ntt203 (emphasis added), JA438.

[16] *Id.*

[17] *Id.*

from e-cigarettes were *significantly lower* than those of tobacco cigarettes."[18] Given the lack of proof of harm, the study advocated "[f]uture research" to "study exposure patterns over extended periods of time and the potential health effects of long-term exposure to secondhand e-cigarette vapors."[19]

DOT reads this call for further inquiry as somehow supporting the agency's contention that e-cigarette vapor might be unsafe. *See* 81 Fed. Reg. at 11420 [JA389] (suggesting that "e-cigarette aerosol" may have "specific hazards," even though they have "not yet been fully identified"). In fact, the studies in the record do not demonstrate that it is even plausible that secondhand exposure to e-cigarette vapor has any hazards whatsoever. Instead, they only speculate that it *might* conceivably turn out to be harmful in the course of future research. DOT makes much of the fact that "three medical associations … cited the unknown health risks of exposure to e-cigarette aerosol in a confined space as a reason for concern," *id.* at 11420 [JA389], but these associations' comments cite no research finding that secondhand exposure to e-cigarette vapor harms human health or has caused passenger discomfort. (One seems to be predicated on the notion that supporters of e-cigarettes should have to prove them harmless with "certainty."[20])

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[18] *Id.* [JA437]

[19] *Id.* [JA438]

[20] *See, e.g.*, Comments of American Cancer Society et al., at 2 [JA356] ("Unless and until it can be shown with a high degree of certainty that e-cigarettes

DOT also cited studies suggesting that e-cigarette vapor may cause thirdhand exposure to nicotine and other substances. But such studies generally involved the vapor emitted by e-cigarettes (which is consumed by users), rather than what users exhale (which is what bystanders are potentially exposed to). DOT said such vapor could result in "persistent residual nicotine on indoor surfaces from e-cigarettes" that "can lead to third hand exposure through the skin, inhalation, and ingestion long after the air itself has cleared." Final Rule, 81 Fed. Reg. at 11420 & n.8 [JA389].

However, the first study cited, Goniewicz & Lee, merely concluded that nicotine is present indoor surfaces exposed to e-cigarette vapor. It did not even address whether, or how, such exposure might affect human health or comfort.[21] The authors note that their findings are "preliminary," with "important limitations," calling for "future research" to "explore the risks of thirdhand exposure from e-cigarettes."[22] "Despite the small emissions of nicotine from e-cigarettes as compared to tobacco cigarettes," the study notes, "e-cigarettes *might*

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pose no such harm to non-users, DOT should prohibit their use") (Comment ID: DOT-OST-2011-0044-0693).

[21] *See* M.L. Goniewicz & L. Lee, *Electronic Cigarettes Are A Source of Thirdhand Exposure to Nicotine*, Nicotine Tob Res. (2014), pii:ntu152 (http://ntr.oxfordjournals.org/content/early/2014/08/28/ntr.ntu152.abstract).

[22] *Id.* at 258, JA434.

be a source of particles and organic compounds that can contaminate the air."[23] (Minute quantities of nicotine do not harm anyone, and as a commenter noted,[24] are found in common foods such as cauliflower, eggplant, potatoes, and tomatoes.[25])

Moreover, the study's simulation did not represent real-world cabin conditions, as the study "did not investigate the effect of exhaled vapors by the users of the products but simulated exposure conditions by releasing vapor manually."[26] This simulation had nothing in common with actual e-cigarette use, and thus exaggerated its risks. As the Schripp study that DOT cited as support for its rule notes, e-cigarettes do not release their vapor directly into the air: "In contrast to the conventional cigarette, which continuously emits particles from the

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[23] *Id.* at 257 (emphasis added), JA433.

[24] Comment of Lynn Ryan-Loeb, comment ID: DOT-OST-2011-0044-0550 (Nov. 7, 2011) (discussing the "nicotine coming from vegetable products such as squash, pumpkins, etc.") (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0550), JA203.

[25] *See* Edward F. Domino, et al., *The Nicotine Content of Common Vegetables*, 329 New Engl. J. Med. 437, Table 1 (1993) (http://www.nejm.org/doi/full/10.1056/NEJM199308053290619#t=article); Rachel Tepper, *Nicotine In Vegetables: 20 Pounds Of Eggplant Equivalent To 1 Cigarette*, Huffington Post, June 14, 2012 (http://www.huffingtonpost.com/2012/06/15/nicotine-in-vegetables_n_1597087.html) (roughly a half pound of cauliflower (263 grams) provides "about as much nicotine as being in a room with a smoker for three hours").

[26] *See* M.L. Goniewicz & L. Lee, *Electronic Cigarettes*, at 258, JA434.

combustion process itself, the e-cigarette aerosol is solely released [into the air] during exhalation."[27] Likewise, the Czogala study DOT relied upon notes that, "no sidestream vapor is generated from e-cigarettes between puffs."[28] In short, while a lit cigarette steadily emits smoke, an e-cigarette only does so when it is puffed, and its vapor is inhaled by the user rather than by bystanders.

Moreover, as another study in the record notes, unlike tobacco cigarettes, which create side-stream smoke that can result in nonsmokers passively inhaling harmful chemicals, the chemicals in e-cigarette vapor are largely absorbed by the user: "Exhaled breath after e-smoking contains even less nicotine per puff, as much of the nicotine inhaled is absorbed. Similarly, propylene glycol is largely absorbed and little is exhaled."[29] And as that study's author had noted in an earlier

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[27] T. Schripp et al., *Does E-Cigarette Consumption Cause Passive Vaping?*, 23 Indoor Air 25, 29 (2013), doi:10.1111/j.1600–0668.2012.00792.x, JA422.

[28] Jan Czogala et al., *Secondhand Exposure to Vapors From Electronic Cigarettes,* 16 Nicotine & Tobacco Research 655, 656 (2014), JA436; *see also id.* at 655 (abstract), JA435.

[29] Murray Laugesen, Health New Zealand, *E-cigarettes: Harmless Inhaled or Exhaled: No Second Hand Smoke* (Sept. 8, 2009). This study is attached as Appendix E (the sixth attachment) to the comments of CASAA and CEI (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0689), JA296. *See also* Murray Laugesen, Health New Zealand, *Safety Report on the Ruyan® e-cigarette Cartridge and Inhaled Aerosol*, at 21 (30 Oct. 2008) ("In contrast [to cigarette smoke], the e-cigarette generates no sidestream smoke") (http://www.healthnz.co.nz/RuyanCartridgeReport30-Oct-08.pdf), linked to and cited in the comment of William T. Godshall, Executive Director, Smokefree Pennsylvania, comment ID: DOT-OST-2011-0044-0713 (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0713), JA373.

publication cited by a commenter, any exhaled "mist visibly dissipates to vapor within seconds. Non-smoking bystanders do not find the mist unpleasant. The mist is odorless."[30]

The second study DOT cites regarding thirdhand exposure, Kuschner et al., does not even state that direct inhalation of the chemicals in e-cigarette vapor is harmful, much less that thirdhand exposure will cause harm,[31] opining that "[i]t is unknown whether inhalation of the complex mixture of chemicals found in ENDS vapors is safe."[32]

As for other substances, to the limited extent that DOT ever identified any research regarding the actual health effects of chemicals contained in e-cigarette vapor, it was in a study DOT wisely did not rely upon in its final rule. That study, cited only in the NPRM, showed that propylene glycol may cause irritation in humans only at over a *thousand* times the concentration of the chemical in

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[30] Murray Laugesen, *Safety Report on the Ruyan® e-cigarette Cartridge and Inhaled Aerosol*, at 21 (30 Oct. 2008) (http://www.healthnz.co.nz/RuyanCartridgeReport30-Oct-08.pdf), linked to and cited in the comment of Godshall (Smokefree Pennsylvania), comment ID: DOT-OST-2011-0044-0713 (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0713), JA373.

[31] W.G. Kuschner et al., *Electronic Cigarettes and Thirdhand Tobacco Smoke: Two Emerging Health Care Challenges for the Primary Care Provider,* 4 Int J Gen Med. 115 (2011), JA412.

[32] *Id.* at 115; *accord id.* at 117 ("Whether inhalation of the complex mixture of chemicals in ENDS vapors is safe is unknown."), JA413.

e-cigarette vapor.[33] This 2001 study, Wieslander et al., discusses the effects of propylene glycol in the context of its use in "artificial smoke generators" and "aviation emergency training"—but *not* in the context of e-cigarettes.[34] The study found evidence that propylene glycol caused irritation to humans at a mean air concentration of 360 *milligrams* per cubic meter.[35] By contrast, in the final rule, DOT cites a more recent study, Schober et al., which found that in an enclosed space, propylene glycol emitted by e-cigarette vapor was present at a mere 140 to 215 *micrograms* per cubic meter—over a *thousand times less* than the concentration that could cause irritation in the Wieslander study.[36] Moreover, as Czogala et al. note, although "e-cigarette vapor contains significant amounts of propylene glycol and vegetable glycerin … both compounds are considered to be safe."[37]

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[33] NPRM, 76 Fed. Reg. at 57010 [JA180].

[34] G. Wieslander et al., *Experimental Exposure to Propylene Glycol Mist in Aviation Emergency Training: Acute Ocular and Respiratory Effects*, at 650, Occupational and Environmental Medicine (2001), JA399.

[35] *Id.* at 652, JA401.

[36] W. Schober et al., *Use of Electronic Cigarettes (E-Cigarettes) Impairs Indoor Air Quality and Increases FeNO Levels of E-Cigarette Consumers,* 217 Int J Hyg Environ Health 628, 633 (2014), JA442.

[37] Czogala at 661, JA438.

As the National Research Council notes, "Propylene glycol … is widely used in foods, cosmetics, and pharmaceuticals."[40] As commenters noted, far from being toxic, propylene glycol has been used in air cleaning systems in hospitals[41] and airplanes,[42] and researchers have said it kills germs and helps prevent the spread of disease.[43]

Besides nicotine and propylene glycol, DOT's final rule cites a study that "detected toxic chemicals" including "formaldehyde," "acetaldehyde" and "acrolein" in the "aerosol from certain e-cigarettes." 81 Fed. Reg. at 11420 & nn.9–10 [JA389]. This study, Goniewicz et al., detected the presence of these chemicals in the vapor emitted by e-cigarette "puffs," but it did not examine

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[40] National Research Council Committee on Air Quality in Passenger Cabins of Commercial Aircraft, *The Airliner Cabin Environment and the Health of Passengers and Crew* (2002), http://www.ncbi.nlm.nih.gov/books/NBK207471/.

[41] *See* Comment of Elaine Keller & Kurt Fritzinger, comment ID: DOT-OST-2011-0044-0691 (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0691), JA322, citing attachment 3 to their comments, O.H. Robertson, *Disinfection of air by germicidal vapors and mists,* 36 Am. J. Public Health 390 (1946), JA325.

[42] *See* Comment of Kimberly A., comment ID: DOT-OST-2011-0044-0585 (Nov. 8, 2011) ("Electronic cigarette vapor … is 90% composed of the same chemical used to clean the recirculated air on an airplane – propylene glycol") (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0585), JA205.

[43] *See* Comment of Elaine Keller & Kurt Fritzinger, *citing* O.H. Robertson, *Disinfection of air by germicidal vapors and mists,* 36 Am J Public Health 390 (1946) (marked reduction in respiratory infections was seen in a 3-year study conducted in a children's convalescent home using propylene and triethylene glycols in an air sanitizing system), JA322, 325-36.

whether such chemicals were present in ambient indoor air exposed to e-cigarette vapor.[44] Nevertheless, the authors explain that their conclusions actually "support the proposition that the vapour from e–cigarettes is less injurious than the smoke from cigarettes."[45] In fact, the study notes that "the levels of potentially toxic compounds in e-cigarette vapour are 9–450-fold lower than those in the smoke from conventional cigarettes, and in many cases comparable with the trace amounts present in pharmaceutical preparation."[46] Nowhere in the study is there any indication that the substances contained in e-cigarette vapor are present at levels remotely close to those known to cause harm or discomfort to humans.[47]

These chemicals are not dangerous in small doses, and indeed, are found in commonly consumed foods and household items. For example, "Formaldehyde is a colorless gas … present in every cell in the human body and in the atmosphere." *Gulf S. Insulation v. U.S. Consumer Prod. Safety Comm'n*, 701 F.2d 1137, 1140 (5th Cir. 1983). It "is nearly ubiquitous in our society," in "building materials, glues and many other common products." *Rutigliano v. Valley Bus. Forms*, 929 F. Supp. 779, 782 (D.N.J. 1996). "It is present in numerous commonly used products

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[44] M.L. Goniewicz et al., *Levels of Selected Carcinogens and Toxicants in Vapour From Electronic Cigarettes*, at 5, 23 Tobacco Control 133 (2013), doi: 10.1136/tobaccocontrol–2012–050859, JA425, JA427.

[45] *Id.* at 6, JA427.

[46] *Id.*

[47] *See generally id.*

such as permanent press clothing, certain textile products … as well as certain draperies and carpeting." *Kuhn v. Skyline Corp*., No. CIV. A. 83-0942, 1984 WL 62775, at *4 (M.D. Pa. Aug. 3, 1984). Acetaldehyde and acrolein are also found in common foods and household items.[48]

Indeed, acetaldehyde is emitted into air cabins as a result of consumption of alcohol, which DOT permits airlines to serve passengers. *See Kaufman v. Director of Revenue,* 193 S.W.3d 300, 301 (Mo. App. 2006) (acetaldehyde released in drinkers' breath); *Goethe v. State*, 668 S.E.2d 859, 860 (Ga. 2008). As one commenter pointed out, "I would much rather be sitting next to a smoker than a drunk. The breath from someone drinking is more harmful and nauseating than

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[48] Klaus Abraham, Susanne Andres, Richard Palavinskas, Katharina Berg, Klaus E. Appel, Alfonso Lampen, *Toxicology and risk assessment of acrolein in food*, Mol. Nutr. Food Res. 2011, vol. 55, pp. 1277–90. doi:10.1002/mnfr.201100481 (noting that French fries contain acrolein); Dept. of Health & Human Services, *Household Products Database: Formaldehyde* (showing soaps, shampoos, laundry detergent, and Aleene's School Glue, contain formaldehyde), https://householdproducts.nlm.nih.gov/cgi-bin/household/brands?tbl=chem&id=110&query=formaldehyde&searchas=TblChemicals; HHS, *Household Products Database: Acetaldehyde* (showing Aleene's School Glue and various other household products contain acetaldehyde), https://householdproducts.nlm.nih.gov/cgi-bin/household/brands?tbl=chem&id=1908&query=acetaldehyde&searchas=TblChemicals.

vapor from an ecigarette and nicotine use doesn't cause idiotic or potentially violent behavior.(although denying someone [access to e-cigarettes] could!).”[49]

As many commenters also noted,[50] it makes no sense for DOT to ban e-cigarettes even as it allows airlines to serve alcohol, which poses greater risks, such

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[49] Comments of Nicole Perry, comment ID: DOT-OST-2011-0044-0290, (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0290), JA194.

[50] *See, e.g.*, Comment ID: DOT-OST-2011-0044-0236 (“Are they going to ban alcohol also? I would much rather myself and my children sat next to a person with an e-cigarette vs a person that is drinking”) (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0236), JA191; Comment ID: DOT-OST-2011-0044-0155 (“Why has alcohol not been banned on flights?”; e-cigarettes “pose no threat to the health of other passengers,” and “allow people who use them to feel comfortable and at ease during travel”) (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0155), JA186; Comments of Josh T. Wood, (“no health hazards” from e-cigarettes, “unlike the alcohol that is pushed on passengers during flights.”) (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0553), JA204; Comments of Mary Lewellyn, ID: DOT-OST-2011-0044-0261 (“ironic that you can serve alcohol on planes but want to ban” e-cigarette that “only emits water vapor. I really don't enjoy sitting next to someone who is drinking”) (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0261), JA193; Comment ID: DOT-OST-2011-0044-0258 (comparing e-cigs to “people who breath alcohol vapor on you[] after drinking a vodka tonic in a plane”; “ the parts per million of water vapor/alcohol/and propylene glycol (the ingredients in a solution of an electronic cigarette, all of which the FDA regulates and are safe for consumption) would not nearly compete with the breathe of someone who just drank”), J192; Comment ID: DOT-OST-2011-0044-0074 (“prefer that you ban alcohol. Far more problems are caused by drunk and unruly fliers”), JA184; Comment ID: DOT-OST-2011-0044-0703 (unlike e-cigarettes, which do not pose “health or comfort concerns,” “I don't really appreciate when someone next to me … is drinking and smells like alcohol.”), JA360; Comments of Melissa Colleen Derrick (“Everytime you serve an alcoholic beverage … you are endangering people MUCH more than the imagined risks of e-cigarette vapor.”) (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0228), JA190; Comment of Joel R. Cederholm (“alcohol on flights” “seems to cause more

as affecting "the behavior of passengers to the point where flights had to be diverted."[51] This disparate treatment is arbitrary and capricious. *See Lilliputian Systems v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309 (D.C. Cir. 2014) (agency acted arbitrarily and capriciously in banning flammable-gas fuel cell cartridges from flights while allowing medicinal and toilet articles containing similar gas; an agency cannot treat similarly situated entities differently unless it "'support[s] th[e] disparate treatment with a reasoned explanation and substantial evidence in the record'"), *quoting Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 777 (D.C. Cir. 2005) (disparate treatment of shippers and carriers was arbitrary and capricious).

DOT also cites a study that identified "22 chemical elements in e-cigarette aerosol, including lead, nickel, and chromium, among others that can cause adverse health effects in the respiratory and nervous systems." 81 Fed. Reg. at 11420 & n.11 [JA389]. Like several other studies cited by DOT, however, this study, Williams et al., found these chemical elements in the e-cigarette puffs that users inhale—*not* what users exhale, or what non-users inhale, or what indoor room air

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problems than anything else.")(https://www.regulations.gov/document?D=DOT-OST-2011-0044-0174).

[51] Anonymous comment, comment ID: DOT-OST-2011-0044-0035 (Sept. 15, 2011), (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0035).

concentrations would result from actual e-cigarette use.[52] In fact, the study noted that "[n]anoparticles of these elements [tin, chromium, and nickel] were not found in samples of room air."[53] The Williams study also observed that its results might not be true of other brands of e-cigarettes, and that "future studies" were needed to determine whether the elements contained in e-cigarette vapor "present long-term health risks to users."[54] As the study noted, because e-cigarettes "do not burn tobacco, they do not produce the numerous chemicals found in conventional tobacco smoke."[55] Thus, e-cigarettes "may help smokers overcome nicotine addiction and/or serve as nicotine delivery devices that are safer than tobacco burning cigarettes."[56]

Fortunately, unlike the Williams et al. and Goniewicz et al. studies, Schober et al. actually "analyz[ed] the indoor air concentration of e-cigarette emissions," which is far more probative of whether secondhand exposure to e-cigarette vapor is harmful to passengers.[57] The study studied indoor air after "six vaping sessions,"

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[52] M. Williams et al., *Metal and Silicate Particles Including Nanoparticles Are Present in Electronic Cigarette Cartomizer Fluid and Aerosol,* 8 Public Library of Science One, at 2 [JA430], e57987 (2013); *id.* at 9 ("Aerosol was produced using [a] smoking machine"), doi:10.1371/journal.pone.0057987.

[53] *Id.* at 4, JA430.

[54] *Id.* at 5, JA431.

[55] *Id.* at 1, JA428.

[56] *Id.*

[57] Schober et al. at 629, JA440.

finding an "increase" in propylene glycol and nicotine.[58] Schober et al. also found that "[f]ormaldehyde, benzene and the pyrolysis products acrolein and acetone *did not* exceed background concentrations," in all the sessions but one.[59] Even this one atypical increase (to 55 µg/m$^3$ or less than 55 ppb)[60] was well below the OSHA "Permissible Exposure Limit" of 750 ppb (0.75 ppm) for an "8-hour" period.[61]

DOT also cites another study, Schripp et al., examining the quality of indoor air exposed to continuous e-cigarette vaping. 81 Fed. Reg. at 11420 & n.13 [JA389]. Despite previous research discussing the "formation of formaldehyde, acetaldehyde, and methylglyoxal in the e-cigarette," the study found only a "slight increase in the formaldehyde concentration in the 8-m$^3$ emission test chamber before and during the consumption" of e-cigarette liquids.[62] The study also notes

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[58] *Id.* at 631, JA441.

[59] *Id.* (emphasis added), JA441.

[60] *See id.* (55 µg/m$^3$); *Microgram/cubic meter ↔ Part per billion Conversion*, http://www.endmemo.com/sconvert/mg_m3ppb.php (providing rough one-to-one conversion from micrograms per cubic meter to parts per billion). This conversion slightly overstates the resulting quantity of formaldehyde in ppb, since 0.37 mg/m$^3$ (which equals 370 µg/m$^3$) of formaldehyde equals 0.3 ppm, or 330 ppb. See OSHA, *Formaldehyde,* https://www.osha.gov/dts/chemicalsampling/data/CH_242600.html (discussing the ACGIH threshold). Thus, the level is actually about 49 ppb (55*330/370=49.05).

[61] 29 C.F.R. § 1910.104(c).

[62] T. Schripp et al., *Does E-Cigarette Consumption Cause Passive Vaping?*, 23 Indoor Air 25, 28 (2013), doi:10.1111/j.1600–0668.2012.00792.x [JA421].

that "[o]ther indoor pollutants of special interest, such as benzene, were only detected during the tobacco smoking experiment."[63]

Ultimately, the studies cited by the agency only show that e-cigarette vapor might introduce into indoor air certain chemicals, some of which, if present in high concentrations, might pose a health risk. But there is no evidence that e-cigarettes are even remotely likely to raise the cabin concentration of any substance to a level where passengers will experience harm or even mild discomfort. Yet DOT ignores "the fundamental tenet of toxicology": that "the dose makes the poison," as Smokefree Pennsylvania pointed out in its comments to the agency.[64]

The final rule cites no evidence in the record that exposure to secondhand e-cigarette vapor emits *any* substances at a concentration sufficient to create a risk of harm, let alone be perceived by passengers. Indeed, as Schober et al. note, it is unclear whether there are any health risks from passive exposure: While it suggested that "[e]xposure to e-cigarette pollutants might be a health concern," it conceded that "[w]hether effects also occur in passive smokers, is uncertain. Recent data … did not indicate alterations induced by passive or even active

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[63] *Id.* at 28, JA421.

[64] Comments of Smokefree Pennsylvania at 3, *Smoking of Electronic Cigarettes on Aircraft* (2011), *available at* https://www.regulations.gov/document?D=DOT-OST-2011-0044-0713, JA373.

vaping of e-cigarettes … Further research is needed to address particularly the issue of potential long-term effects of e-cigarette use."[65]

Moreover, any air cabin contaminant levels from e-cigarettes are minute compared to pre-existing levels of contaminants in air cabins found by the Federal Aviation Administration. *See* FAA, Office of Aerospace Medicine, *Aircraft Cabin Bleed Air Contaminants: A Review* (DOT/FAA/AM-15/20, Nov. 2015), https://www.faa.gov/data_research/research/med_humanfacs/oamtechreports/2010s/media/201520.pdf. Such contaminants include "particles" that "may result in a variety of adverse health effects that range from irritation of eyes, nose, and throat to respiratory and other system disorders."[66]

Yet the FAA's response to such levels was not to call for a ban on the most common sources of such contamination. Instead, it called for further study, focusing on the rare flight (a mere one in every 30,000 flights) where contaminants rise beyond typical levels so extremely as to trigger a "contaminated air event."[67] Absent such a study, "Quantification of the potential health risks associated with exposure to bleed-air contaminants in cabin air is not possible."[68]

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[65] Schober et al. at 636, JA444.

[66] *Id.* at 4–5 ("Maximum concentrations from all flights ranged from 1 to 312,000 p/cm3.")

[67] *Id.* at 5.

[68] *Id.* at 5.

But low concentrations of contaminants would not lead to a "contaminated air event." As FAA noted in that report, low levels of contaminants often have no adverse health effects. Air cabins already contain carbon monoxide, but these levels (between "0.2 and 2.9 ppm") of "CO concentrations inside an aircraft are typically below levels associated with adverse health effects."[69] Similarly, ozone, "a toxic gas,"[70] is present in air cabins: "Exposure to $O_3$ may be associated with symptoms ranging from irritation to eyes and mucous membranes to chronic respiratory disease"; in one study of 68 flights, "peak hour $O_3$ measurements ranged from 3 to 275 ppb," while another found "the average $O_3$ concentration was 15.9 ppb."[71] Such levels should "not exceed" 100 ppb "for any three-hour period when the aircraft is above 27,000 feet" or "250 ppb when the aircraft is above 32,000."[72]

This level of ozone DOT deems permissible is higher than the indoor air concentrations of less dangerous chemicals found in the e-cigarette studies relied upon by DOT, such as the 55 ppb of formaldehyde found as a maximal outlier in the Schober study (which found an increase in its air concentration in only one of

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[69] *Id.* at 3.

[70] EPA, *Ozone Generators That Are Sold as Air Cleaners* ("Ozone is a toxic gas"), https://www.epa.gov/indoor-air-quality-iaq/ozone-generators-are-sold-air-cleaners.

[71] FAA, *Aircraft Cabin Bleed Air Contaminants: A Review*, at 3.

[72] *Id.* at 3.

six vaping sessions). The government sets a much lower permissible level for exposure to ozone than to formaldehyde.[73] The government has cited the presence of acetaldehyde and acrolein in the vapor inhaled by e-cigarette users (not necessarily in indoor air concentrations); but those chemicals are less dangerous (in the case of acetaldehyde), or no more dangerous, than ozone; the government sets a much higher level of permissible exposure for acetaldehyde than for ozone, and the same or higher level for acrolein versus ozone.[74]

As FAA noted, the vapors already found in air cabins include chemicals such as benzene and styrene (which are carcinogens[75]) and hexane and methylene chloride (which are neurotoxicants[76]): "Vapors contained in contaminated cockpit/cabin air may include both volatile and semi-volatile organic compounds (VOCs and SVOCs)"; a study "measured 64 VOCs in aircraft cabins during 83

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[73] *See* 29 CFR § 1910.1000 Table Z-1 (OSHA Permissible Exposure Limit for ozone is 0.2 mg/m$^3$ or 0.1 ppm (100 ppb)); 29 C.F.R. 1910.104(c) (OSHA "Permissible Exposure Limit" for formaldehyde of 750 ppb (0.75 ppm).

[74] *See* 29 CFR 1910.1000 Table Z-1 (OSHA Permissible Exposure Limit for acetaldehyde is 360 mg/m$^3$ or 200 ppm (20,000 ppb) while acrolein is 0.25 mg/m$^3$ or 0.1 ppm (100 ppb)).

[75] *See* NIH, *Report on Carcinogens, Thirteenth Edition*, https://ntp.niehs.nih.gov/ntp/roc/content/profiles/styrene.pdf (styrene), https://ntp.niehs.nih.gov/ntp/roc/content/profiles/benzene.pdf (benzene).

[76] *See* EPA, *Methylene Chloride: Dichloromethane* (Jan. 2000) https://www3.epa.gov/airtoxics/hlthef/methylen.html (also "probable human carcinogen"); *Hexane*, Toxipedia (http://www.toxipedia.org/display/toxipedia/Hexane).

flights … 91% contained toluene, 90% contained carbon tetrachloride and tetrachloroethene, 75% contained m- and p-xylene, and 50 to 75% contained benzene, ethylbenzene, o-xylene, methylene chloride, hexane, and styrene."[77] Concentrations of compounds such as benzene, styrene, and o-xylene measured "on some flights were substantially higher than concentrations expected in offices and homes," even "under routine operating conditions."[78] But FAA did not propose any regulations based on trace quantities of such chemicals.

### C. DOT Failed Even to Consider Studies Cited By Petitioners Showing No Risk or Harm from E-Cigarettes

DOT also did not discuss, let alone analyze, the studies submitted by petitioners showing that e-cigarettes cause no harm, and likely pose no risk to health, much less a significant risk, and do not produce a bad smell (unlike tobacco smoke), much less affect passenger comfort. Nor, with one exception, did it even mention them in passing.[79]

This was improper, since agencies have been found to have acted arbitrarily and capriciously where they "failed to respond" to contrary information submitted by opponents of a rule or were "ducking serious evaluation" of studies they

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[77] *Aircraft Cabin Bleed Air Contaminants: A Review*, at 4.

[78] *Id.* at 4.

[79] It did mention in passing a Health New Zealand study showing e-cigarette mist does not contain any of "over 50 cigarette smoke Toxicants." 81 Fed. Reg. at 11418–19 [JA387-88].

submitted. *Business Roundtable v. S.E.C.,* 647 F.3d 1144, 1152 (D.C. Cir. 2011). An agency must "explain why it has rejected or ignored contradictory evidence." *Islander East Pipeline Co. v. Connecticut Dept. of Environmental Protection*, 482 F.3d 79, 100 (2d Cir. 2006).

As a study submitted by petitioners noted, "none of the more than 10,000 chemicals present in tobacco smoke, including over 40 known carcinogens, has been shown to be present in the cartridges or vapor of electronic cigarettes in anything greater than trace quantities. No one has reported adverse effects, although this product has been on the market for more than 3 years." Zachary Cahn & Michael Siegel, *Electronic Cigarettes as a Harm Reduction Strategy For Tobacco Control: A Step Forward or a Repeat of Past Mistakes?*, 2010 Journal of Public Health Policy 1–16, at 11 [JA232]. The minute "levels of these carcinogens" in e-cigarettes is "similar to that in NRT [Nicotine Replacement Therapy] products" that the FDA authorizes as safe, *id.,* and thus "electronic cigarettes show tremendous promise in the fight against tobacco-related morbidity and mortality."[80] But DOT did not mention this opposing evidence, much less seriously evaluate it.

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[80] *Id.* abstract [JA222]. *See also id.* at 3 ("Other than TSNAs and DEG, few, if any, chemicals at levels detected in electronic cigarettes raise serious health concerns"; "TSNAs have been detected in two studies at trace levels. … none of the other 15 studies found any DEG."), JA224. This study was submitted as Appendix A (the second attachment) to the comments of CASAA and CEI, *see*

As a report from Health New Zealand submitted by petitioners noted,

> Second hand mist from an e-cigarette is not smoke at all, and does not contain any substance known to cause death, short or long term, in the quantities found. It becomes invisible within a few seconds, and is not detectable by smell. . .The e-cigarette does not create side-stream smoke. Exhaled breath after e-smoking contains even less nicotine per puff, as much of the nicotine inhaled is absorbed. Similarly, propylene glycol is largely absorbed and little is exhaled. No harm found in e-cigarette mist. Nicotine is not harmful in the quantities mentioned. Propylene glycol is harmless – it is used in making theatrical fog and as an ingredient in soaps, personal lubricants and intravenous medicines.

Health New Zealand, *E-Cigarettes: Harmless Inhaled or Exhaled: No Second Hand Smoke* (2009) (citing Murray R.P., Bailey W.C., Daniels K. et al., *Safety of Nicotine Polacrilex Gum Used By 3,094 Participants in the Lung Health Study*, LHS Research Group. Chest 1996; 102: 438–45), JA 296-97.

If what little "second hand mist" even exists "is not detectable by smell," and "becomes invisible within a few seconds," with e-cigarette vapor being "largely absorbed" rather than "exhaled," it is hard to understand how it could possibly affect passenger comfort, much less do so significantly. This study's findings about the effects of propylene glycol were echoed by other materials submitted by petitioners. In one, EPA found propylene glycol to be safe, noting that "EPA has concluded that there are no endpoints of concern for oral, dermal, or

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Docket No. DOT-OST-2011-0044, comment ID: DOT-OST-2011-0044-0689 (Nov. 14, 2011) (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0689)

inhalation exposure to propylene glycol and dipropylene glycol," and "there is a reasonable certainty of no harm for infants and children"[81]; in the other, a study found exposure to vastly greater quantities of propylene glycol to produce visible theatrical effects not to have significant health effects.[82]

Similarly, EPA ignored the studies cited by William T. Godshall, MPH, the Executive Director of Smokefree Pennsylvania. As he noted, a "Literature Review for Glycerol and Glycols for Entertainment Services & Technology Association . . . found no health risks to humans" from exposure to propylene glycol.[83] It noted that the "Food and Drug Administration (FDA) has classified PG [propylene glycol] as a Generally Recognized as Safe (GRAS) additive. GRAS additives are

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[81] EPA, *Reregistration Eligibility Decision for Propylene Glycol and Dipropylene Glycol* at 16 (Aug. 2006) (finding propylene glycol basically safe); *see* fifth attachment ("App. E.") to comments of CEI and CASAA, containing this EPA decision, *see* comment ID: DOT-OST-2011-0044-0689 (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0689), JA289.

[82] *See* Jacqueline M. Moline & Anne L. Golden, *Health Effects Evaluation of Theatrical Smoke, Haze & Pyrotechnics* (prepared for Equity-League and Pension Health Trust Funds) (June 6, 2000), at ES-6 ("No evidence of serious health effects was found to be associated with exposure to any of the theatrical effects evaluated in this study," which involved exposure to very large amounts of propylene glycol to generate substantial amounts of visible fog); *see* Appendix C (fourth attachment) to comments of CASAA & CEI, containing this study, JA253.

[83] William T. Godshall comments (Nov. 14, 2011) at pg. 3 (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0713), JA373, *citing Literature Review for Glycerol and Glycols for Entertainment Services & Technology Association.* This report is available at http://www.sfata.org/wp-content/uploads/2013/06/Literature-review-for-Glycerol-and-Glycols.pdf.

materials which are virtually indistinguishable from foods. . . .These substances may be added in relatively substantial amounts to food, in some instances at levels representing more than 1 percent of dietary intake. The FDA considers an average daily dietary intake of 23 mg/kg of body weight of PG to be safe for persons 2 to 65 years of age."[84] In food, the concentrations range up to "15% in some seasonings and flavorings. It is also used as a humectant or moistening agent in foods, such as shredded coconut."[85] Propylene glycol "has been used extensively in food and pharmaceuticals . . .The hazards to health in the industrial handling and use of PG seem to be negligible."[86] Moreover, "it is felt that the inhalation of atmospheres containing PG presents no hazard to health"; "Studies have been done in hospital wards using PG in an air-sterilization application. In these studies, humans were exposed to saturated and super saturated atmospheres for prolonged periods without adverse effects."[87] "Robertson and coworkers (1947) exposed monkeys and rats to atmospheres saturated with PG vapor and found no adverse

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[84] *Literature Review for Glycerol and Glycols for Entertainment Services & Technology Association*, at 6-7, citing Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services, *Case Studies in Environmental Medicine for Ethylene and Propylene Glycol Toxicity # 30* (Sept. 1993).

[85] *Literature Review* at 7.

[86] *Id.*

[87] *Id.* at 7, *citing* Patty's Industrial Hygiene and Toxicology, volume 2F, 4th edition. G.D. and F.E. Clayton, editors. John Wiley & Sons, New York, NY (1994) p:4645-4719.

effects in animals after periods of 12 to 18 months."[88] (Similarly, Godshall's comment stated that studies "found that laboratory animals were not harmed by very high levels of propylene glycol aerosol."[89])

But DOT failed to cite, let alone address, these studies, or the 13 other studies or laboratory reports linked to by Godshall.[90] For example, it did not address a study he cited noting that any exhaled "mist visibly dissipates to vapor within seconds. Non-smoking bystanders do not find the mist unpleasant. The mist is odorless."[91] (DOT did cite—but did not respond to or seriously evaluate—another report cited by petitioners which noted that "e-cigarette mist," unlike

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[88] *Literature Review* at 8, *citing* Robertson, O.H., Loosli, C.G. Loosli, Puck, T.T., Wise, H., Lemon, H.M., and Lester, W., Jr. (1947). *Tests for the Chronic Toxicity of Propylene Glycol and Triethylene Glycol on Monkeys and Rats by Vapor Inhalation and Oral Administration*. J of Pharmaceutical and Experimental Therapeutics. 91: 52-76.

[89] Godshall comments at 3 [JA373].

[90] *See id.* at 3 (providing hyperlinks to 14 articles; stating that studies and laboratory reports on the "contents of e-cigarettes have found that all [chemical] constituents are present at nonhazardous levels," and providing links to 12 articles in support of that statement).

[91] Murray Laugesen, *Safety Report on the Ruyan® e-cigarette Cartridge and Inhaled Aerosol*, at 21 (30 Oct. 2008) (http://www.healthnz.co.nz/RuyanCartridgeReport30-Oct-08.pdf), linked to and cited in the comment of William T. Godshall, Comment ID: DOT-OST-2011-0044-0713, (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0713), JA373.

tobacco smoke, does not contain any trace of "50 priority-listed cigarette smoke toxicants."[92] *See* 81 Fed. Reg. at 11418–19 [JA387-88].

### D. DOT Failed to Consider Countervailing Comfort and Safety Benefits From Allowing E-Cigarettes

DOT also simply ignored petitioners' arguments about the passenger comfort and health and safety benefits of *allowing* e-cigarettes, which reduces air rage, withdrawal symptoms, and road-related mortality.

This was improper, since "an agency rule" is "arbitrary and capricious if the agency ... entirely failed to consider an important aspect of the problem." *Motor Vehicles Manufacturers Association v. State Farm*, 463 U.S. 29, 43 (1983). DOT acted arbitrarily and capriciously when it ignored "harms that" its rule "might do to human health." *See Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015).

As Petitioners noted in their comments,[93]

> DOT is ignoring the clear benefits of permitting the in-flight use of ecigarettes. First, as the Vansickel study and other reports indicate, e-

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[92] Murray Laugesen, Health New Zealand Ltd, *Ruyan® E-cigarette Bench-top Tests*, Society for Research on Nicotine and Tobacco (SRNT) Dublin, April 30, 2009 ("e-cigarette mist tested for over 50 priority-listed cigarette smoke toxicants so far, no such toxicant was found.").

[93] Comments of CASAA and CEI, comment ID: DOT-OST-2011-0044-0689 (Nov. 14, 2011), 1st attachment, at pg. 4, JA220, JA304 (https://www.regulations.gov/document?D=DOT-OST-2011-0044-0689), citing Andrea R. Vansickel, Caroline O. Cobb, Michael F. Weaver, and Thomas E. Eissenberg, *A Clinical Laboratory Model for Evaluating the Acute Effects of Electronic "Cigarettes": Nicotine Delivery Profile and Cardiovascular and Subjective Effects*, American Association for Cancer Research Journal (July 20,

> cigarettes can alleviate the tobacco withdrawal symptoms faced by smokers on flights. According to one travel website, "it has recently been recognized that a common cause of air rage is nicotine withdrawal in heavy smokers on long-distance 'no smoking' flights…" The Travel Doctor, http://www.traveldoctor.co.uk/flights.htm. But the growing popularity of e-cigarettes indicates that many smokers prefer them to other non-combustion nicotine delivery systems. Allowing their in-flight use would make many smokers far more comfortable on flights. Secondly, many smokers do not fly precisely because they find the prospect of flying uncomfortable due to their inability to smoke on those flights (which may well involve long airport waits and connecting flights as well). See, for example, "Smokers: No Butts, It's A Drag Smokers Are Coping With No-smoking Bans On Some Domestic Flights: They Drive, Schedule Layovers Or Stay Home", Orlando Sentinel (Feb. 7, 1993), http://articles.orlandosentinel.com/1993-02-07/travel/9302030027_1_smoking-layover-airport.
>
> The possibility of inflight e-cigarette use may well induce them to fly when they otherwise would have driven. Given that commercial flights are far safer than driving, especially over long distances, this increase in flying by such smokers could well save lives. (On the basis of deaths per passenger mile travelled, air travel is at nearly 200 times safer than car travel. http://www.airlinereporter.com/2010/09/flying-is-safe-and-i-am-going-to-prove-it/.

As federal agencies have recognized, even modest percentage reductions in air travel by people who drive instead can result in thousands of deaths. As the TSA has noted, a study estimated that "at least 1,200 additional driving deaths

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2010), 10.1158/1055-9965.EPI-10-0288, pg. 7 ("the two products tested in this study produced some tobacco abstinence symptom suppression … In spite of delivering no measurable nicotine, both electronic cigarettes tested in this study reduced ratings of 'craving a cigarette' and 'urge to smoke'") (this study is enclosed as Appendix F (the seventh attachment) to the comments of CASAA and CEI, JA298, JA304), Katsuyuki Miura, et al., *Safety Assessment of Electronic Cigarettes in Smokers*, Seikatsu Eisei, Vol. 55, No. 1 (2011), JA307.

were attributable to the effect of 9/11 as people substituted less-safe surface transportation for safer air transportation."[94] That study attributed "an increase of 242 driving fatalities per month to additional road travel undertaken in response to 9/11."[95] Even back in 1979-1986, when air travel was not as safe, "about 1,700 fewer fatalities per year" were occurring due to airline deregulation that had reduced road travel in favor of air travel by about 3.9%, since "air travel, measured in deaths per air mile traveled, [was] more than 30 times safer than passenger-car."[96] Yet DOT did not even address discuss the subject of road-related mortality.

One of the very statutes that DOT cites as a source of its "authority" to issue the rule[97] is 49 U.S.C. § 40113, which states that "[t]he Secretary of Transportation … may take action the Secretary, or Administrator, as *appropriate*, considers *necessary* to carry out this part, including conducting investigations,

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[94] Transportation Security Administration, *Passenger Screening Using Advanced Imaging Technology: Regulatory Impact Analysis and Final Regulatory Flexibility Analysis*, at 133 (Feb. 18, 2016), (https://www.regulations.gov/document?D=TSA-2013-0004-5583), citing Blalock et al, *The Impact of 9/11 on Road Fatalities: The Other Lives Lost to Terrorism*, at abstract and 1 (Feb. 2, 2005), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=677549.

[95] Blalock et al, *The Impact of 9/11 on Road Fatalities: The Other Lives Lost to Terrorism*, Abstract (Feb. 2, 2005), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=677549.

[96] *Id.* at 7 n.8 (citing Richard B. McKenzie & John T. Warner, *The Impact of Airline Deregulation on Highway Safety* (St. Louis: Center for the Study of American Business, Washington University, 1987)).

[97] *See* 81 Fed. Reg. at 11427 [JA396].

prescribing regulations, standards, and procedures, and issuing orders" (emphasis added).

This language resembles the "appropriate and necessary" provision of the Clean Air Act, 42 U.S.C. § 7412(n)(1)(A), which the Supreme Court interpreted as requiring an agency to consider the costs and negative health effects of its rule, in *Michigan v. EPA*, 135 S.Ct. 2699 (2015). That provision states that "[t]he [EPA] Administrator shall regulate electric utility steam generating units under this section, if the Administrator finds such regulation is appropriate and necessary." The Supreme Court held that "EPA strayed far beyond those bounds when it read § 7412(n)(1) to mean that it could ignore cost when deciding whether to regulate power plants." 135 S.Ct. at 2707. The Court noted that "the phrase 'appropriate and necessary' requires at least some attention to cost." And "costs" includes "harms that" a rule "might do to human health." Indeed, the term "'cost' includes more than the expense of complying with regulations; any disadvantage could be termed a cost." *Id.*

DOT does concede the potential for its rule to cause smokers to substitute driving for flying, noting that "[g]iven that smokers will not have a smoking flight alternative … , they will need to choose another transportation mode such as driving to their destination or if an alternative mode is not feasible, they would need to choose to not travel at all." 81 Fed. Reg. at 11425–26 [JA394-95]. Yet

DOT failed to consider the most important cost associated with this substitution: its effect on mortality, as smokers who choose to drive instead of fly—and anyone traveling with them—are at an increased risk of dying or being injured in an automobile accident.

DOT also failed to consider the health and safety benefit from e-cigarettes of reducing air rage—even though this is an important phenomenon that affects not just nicotine users themselves, but also the safety of other passengers and flight crew. As one aviation law treatise notes, "passengers, flight crew and even the aircraft itself may be endangered from an act of air rage. The number of air rage incidents rises considerably every year. Many factors are thought to be involved," including "nicotine withdrawal."[98] *See also United States v. Tabacca*, 924 F.2d 906, 909 (9th Cir. 1991) (smoker prevented from smoking attacked flight attendant, who was "put on medical leave" due to her injuries).

### E. DOT Arbitrarily Issued Its Rule Despite the Fact That Airlines Already Restrict Vaping

As DOT admits, "the industry has generally banned the use of electronic cigarettes on flights …" Final Rule, 81 Fed. Reg. at 11421 [JA390]. In short, faced with actions by the airlines themselves that removed whatever weak rationale

[98] Michael W. Pearson & Daniel S. Riley, *Foundations of Aviation Law*, at 204 (2016) (https://goo.gl/3EkFCy).

might otherwise exist for its rule, DOT pushed forward nonetheless. That in itself is reason to vacate its action.[99]

But DOT refused to allow this fact to affect its decision, stating that "we do not believe that a free-market approach is appropriate or desirable." This approach is contrary to the mandate of the 1978 Airline Deregulation Act, Pub. L. 95-504, that DOT "plac[e] maximum reliance on competitive market forces and on actual and potential competition …." 49 U.S.C. § 40101(a)(6).

DOT appears to be concerned that, in the future, "some carriers may feel free to adopt policies that allow" vaping. *Id.* [JA390]. But if this were to create any problem at all, such as perhaps some passengers being caught unaware by these policies, DOT could deal with them at that point, such as by mandating certain notice requirements for carriers that permit vaping.

This is in addition to the fact that DOT did not point to any actual harm that had been caused by e-cigarettes (or even cite any actual incident of a passenger experiencing discomfort due to e-cigarettes). Instead, DOT merely speculated that "passengers *may* reasonably be concerned that they are inhaling unknown

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[99] See ICC Decision, *Limitation of Consumption of Alcoholic Beverages on Buses*, 1991 WL 108072, *2 (Jan. 4, 1991) (rejecting petition for an alcohol consumption ban on buses, since "carriers already have taken steps to prohibit consumption of alcoholic beverages on board scheduled buses," thus undercutting the claim that there is "any real problem.").

quantities of harmful chemicals" and a "non-user passenger *may* feel the direct effects of inhaling the aerosol." *Id.* at 11421 (emphasis added), JA390.

DOT's speculation about what passengers "may" feel or "may" be concerned about, *see id.* at 11421, was insufficient to meet the agency's burden. A rule is not justified when the agency claims a regulation will "ameliorate[] a real industry problem but then cit[es] no evidence demonstrating that there is in fact an industry problem." *Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 843–44 (D.C. Cir. 2006). An agency may not engage in "speculation" in determining whether to promulgate a rule. *Horsehead Res. Dev. Co. v. Browner*, 16 F.3d 1246, 1269 (D.C. Cir. 1994). Here, DOT has essentially piled speculation on speculation in assuming a need for this rule.

## III. E-Cigarette Use Cannot Be Banned as an Air Carrier's Unfair or Deceptive Practice Under 49 U.S.C. § 41712

DOT cannot rely on the statute banning an "air carrier" from "engag[ing] in an unfair or deceptive practice … in air transportation," 49 U.S.C. § 41712, to ban e-cigarettes for several reasons: It never provided notice in the Notice of Proposed Rulemaking that it would rely on this statute (or anything like it), the statute only applies to airline conduct, not customer conduct; and electronic cigarettes are not harmful to passengers in any cognizable way, much less misleading in the sense banned by this statute.

### A. DOT Failed to Provide Any Notice That It Might Rely on This Statute to Ban E-Cigarettes

DOT cannot rely on the statute banning an "air carrier" from "engag[ing] in an unfair or deceptive practice … in air transportation," 49 U.S.C. § 41712, because it never so much as hinted at doing so in the Notice of Proposed Rulemaking. Section 553 of the Administrative Procedure Act requires that an NPRM "include ... either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). The notice required under the APA must be "'sufficient to fairly apprise interested parties' of all significant subjects and issues involved." *Am. Iron & Steel Inst. v. EPA*, 568 F.2d 284, 291 (3d Cir. 1977); *see Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014) ("deficient notice is a 'fundamental flaw' that almost always requires vacatur"); *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (APA forbids "agencies to use the rulemaking process to pull a surprise switcheroo on regulated entities").

There could hardly be a more "significant subject" or "issue involved" in the rule than the very statute under which the agency purports to regulate.

An agency is required to renotice its rule, before issuing a final rule, when the original notice did not adequately frame the subjects for discussion. *Conn. Light & Power Co. v. NRC*, 673 F.2d 525, 533 (D.C. Cir. 1982); *see also Omnipoint Corp. v. FCC*, 78 F.3d 620, 632 (D.C. Cir. 1996). No such renotice

occurred here, even though the agency took over four years after the NPRM to issue its final rule.

An agency's final rule may not redefine a statutory term when it has "neither stated nor suggested that [it] was contemplating amending the [definition]." *Daimler Trucks N. Am. LLC v. EPA*, 737 F.3d 95, 102 (D.C. Cir. 2013). Here, it has radically expanded the reach of the "unfair or deceptive practices" statute by applying it to not just non-misleading conduct (a major expansion in and of itself) but also applying it to restrict the conduct of passengers (not just airlines and their agents), as we explain in the next section.

It does not appear that any commenter even anticipated this argument for banning e-cigarettes, or even mentioned this statute. Even if they had, that would not be enough for the agency to rely on it. The agency "must itself provide notice of [its] proposal." *Association of Priv. Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 462 (D.C. Cir. 2012). Even if "some commenters actually submitted comments" addressing this argument, that would be "of little significance" because the agency "must itself provide notice of [its] proposal." *Id.*; *see also Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983) (agency "cannot bootstrap notice from a comment").

### B. This Statute Only Bans "Air Carrier" Conduct, Which Does Not Reach Customer Conduct Like E-Cigarette Use, Even If Such Conduct Were Deceptive or Unfair, Which It Is Not

This statute simply does not reach passenger's use of electronic cigarettes, which is beyond DOT's power to punish. The consumer fraud statute bans an "*air carrier*" from "engag[ing] in an unfair or deceptive practice … in air transportation," 49 U.S.C. § 41712 (emphasis added), not a customer. Yet DOT's rule applies against *customers*, effectively reading the word "air carrier" out of this statute. DOT imposes penalties for violating its smoking ban directly on passengers[103]— the very people who are supposed to be protected by this consumer fraud statute.

DOT cites its "Tarmac Delay Rule" as precedent, *see* Final Rule, 81 Fed. Reg. at 11421 [JA390], but that rule involved unfair conduct by an airline itself and its agents, not customers. Moreover, that conduct left a misleading impression of on-time departures. As DOT explained in its "Tarmac Delay Rule," "Without this requirement, a carrier's advertising of on time performance could be very misleading and consumers would not have any basis for determining whether a statistic provided by a carrier is trustworthy or even relevant to their particular

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[103] *See, e.g.*, 49 U.S.C. § 46301(a)(5)(D) (fine for violating § 41712); 14 C.F.R. § 121.317(g) ("no person may smoke … ."); 81 Fed. Reg. at 11427 (adding new 14 C.F.R. § 252.3 (Smoking means the use of … electronic cigarettes whether or not they are a tobacco product"), JA396.

circumstance." DOT, *Enhancing Airline Passenger Protections*, 74 Fed. Reg. 68983, 68994 (Dec. 30, 2014). By contrast, there is nothing misleading or fraudulent about using an e-cigarette, even if some people actually find e-cigarettes objectionable. No one expects an airline to protect a traveler from *all* unpleasant stimuli from fellow passengers.

Even if a fellow passenger's e-cigarette use could somehow be depicted as "unfair," Section 41712 is not an all-purpose "unfairness" statute: as DOT has recognized in the past, its authority under this statute is "not so broad, however, that it permits action against any and all conduct that could be characterized as unfair." *American Society of Travel Agents. v. Delta Airlines, Inc.*, Order 2002-9-2, 2002 WL 32341072, *16 (Sept. 4, 2002) (observing that even some anti-competitive practices are beyond DOT's reach).

DOT's new rule is a breathtaking expansion of the reach of § 41712 in another way as well. DOT's rule is aimed *against* customers, the very people protected by the consumer fraud statute, rather than against airlines that deceive them. That is a huge departure from the basic nature of laws against consumer fraud, or unfair or deceptive practices, which are designed to protect consumers against businesses—not against each other—and which cover only the conduct of businesses and their agents—not their customers, such as passengers. *See, e.g.*,

*Knutsen v. Dion*, 90 A.3d 866, 871–72 (Vt. 2013) (realtor association not liable for consumer fraud for their model contract when it was used by home seller against purchaser); *Fair Deals Ltd v. World Choice Travel,* 180 F. Supp. 2d 678, 684–85 (D. Md. 2001) (Lanham Act did not reach conduct of non-agent); *Raclaw v. Fay, Conmy & Co.*, 668 N.E.2d 114, 117 (Ill. App. 1996) (No liability where institution did not hold wrongdoer "out as its agent" for the activity in question). A company's customers are not its agents. *Scola v. U.S. Sprint Communications*, No. 87-1567, 1988 WL 19656, *4 (N.D. Ill. Feb. 26, 1988).

A ban on unfairness by an entity generally only applies to it and its agents. *See, e.g.*, *Blum v. Yaretsky*, 457 U.S. 991, 1002-04 (1982) (state officials not liable under the Fourteenth Amendment for unfair discharges of Medicaid patients by taxpayer-funded nursing homes that were "extensively regulated" by the state's Medicaid Program; their "mere approval of or acquiescence in the initiatives of a private party," "however discriminatory or wrongful" that party's conduct, did not give rise to liability); *Moose Lodge v. Irvis*, 407 U.S. 163, 176–77 (1972) (no liability under equal protection clause).

### C. DOT Relies On Supposed Harms That Are Not Legally Cognizable and And Fail Its Own Criteria for Regulation of "Unfair" Practices

As DOT itself describes its authority under this statute, "the Department has found practices to be 'unfair' if they are harmful to passengers but could not be

reasonably avoided by them." Final Rule, 81 Fed. Reg. at 11421 [JA390]. But there is no evidence (as opposed to speculation) that e-cigarette vapor is actually harmful to airline passengers in the tiny quantities they will likely be exposed to during a flight.

Such speculative harms have been held to be beyond the reach of unfair trade practices statutes even when they are committed by the seller, as opposed to one's fellow customers. That is illustrated by the reach of the FTC's authority under the similar language found in Section 5 of the Federal Trade Commission Act,[104] which DOT has conceded "is the mold from which section 41712 was cast,"[105] and is the statute on which "Congress modeled" 49 U.S.C. § 41712.[106] As the FTC has explained, the "unfairness" language of the FTC Act does not reach "trivial or merely speculative harms. … Emotional impact and other more subjective types of harm … will not ordinarily make a practice unfair."[107] DOT has

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[104] 5 U.S.C. § 45(a)(2).

[105] See DOT, *Third-Party Enforcement Complaint of the Electronic Privacy Information Center Against Northwest Airlines, Inc. Alleging Violation of 49 U.S.C. § 41712*, Order 2004-9-13, 2004 WL 2049588, *3 (Sept. 10, 20014 (Order dismissing Complaint).

[106] *American Society of Travel Agents v. Delta Airlines*, Order 2002-9-2, 2002 WL 32341072, *16 (Sept. 4, 2002).

[107] Letter from FTC to the Consumer Subcommittee, Senate Committee on Commerce, Science and Transportation (Dec. 17, 1980), appended to International Harvester Co., 104 F.T.C. 949, 1070 (1984).

likewise recognized in the past that 49 U.S.C. § 41712 does not reach "speculative" harms.[108]

Moreover, as DOT has noted in the past, this statute must not be interpreted so expansively as to "frustrate Congress' decision [in the Airline Deregulation Act] that the public will benefit if airline fares and services are determined by market forces rather than government regulation." *Association of Discount Travel Brokers v. Continental/Eastern Tariff*, Order 92-5-60, 1992 WL 133179, at *12 (D.O.T. May 29, 1992). Allowing DOT to override market forces anytime some passengers benefit more from an airline policy than other passengers would completely defeat Congress's intent in passing the ADA.

Moreover, the "harm" DOT cites is not any cognizable harm to human health (as we previously discussed), but merely confusion by ignorant passengers who think they are being exposed to tobacco "cigarette smoke," when in fact they are only witnessing the use of e-cigarettes: It treats as "harms" targeted by its rule "confusion about whether the passenger is being exposed to traditional cigarette smoke." *Id.* at 11421. As DOT puts it, "Passengers who do not … understand the process of e-cigarette use can easily mistake the act for traditional smoking." 81

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[108] DOT, *American Society of Travel Agents, supra*, 2002 WL 32341072, *18, *19 (Sept. 4, 2002) (allegations of injury "too speculative" to support enforcement action); *accord* DOT, *Third-Party Enforcement Complaint of the Electronic Privacy Information Center*, 2004 WL 2049588, at *8.

Fed. Reg. at 11424 [JA393]. Any such confusion or related "emotional impact" is simply too "subjective" to support a violation.[109]

Moreover, any such "confusion" could easily be dispelled (thus rendering any harm "reasonably avoided") just by explaining that e-cigarettes, unlike tobacco cigarettes, are permitted, because they do not emit harmful tobacco smoke.[110]

## CONCLUSION

For the foregoing reasons, DOT's order should be overturned and its rule vacated.

Respectfully submitted this 22nd day of November, 2016,

/s/ Hans Bader

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[109] *See* Letter from FTC, *supra*.

[110] *See, e.g.,* comment of A. Ko, Comment ID: DOT-OST-2011-0044-0009, JA183.

## CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), I certify that:

This brief complies with the type-volume limitation of Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure, because this brief contains 13,869 words, excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii) of the Federal Rules of Appellate Procedure and Circuit Rule 32(a)(1).

This brief complies with the typeface requirements of Rule 32(a)(5) of the Federal Rules of Appellate Procedure and the type-style requirements of Rule 32(a)(6) of the Federal Rules of Appellate Procedure because this brief has been prepared in a proportionately spaced typeface using the 2010 version of Microsoft Word in fourteen-point Times New Roman font.

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## CERTIFICATE OF SERVICE

I certify that on this 22nd day of November 2016, I filed the foregoing brief with the Court. I further certify that on this 22nd day of November 2016, I served the foregoing brief on all counsel of record through the Court's CM/ECF system.

Respondent's counsel, who have appeared, will be automatically served by the CM/ECF system, including:

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