

Nos. 19-2130 [L], 19-2132, 19-2198, 19-2242

**IN THE UNITED STATES COURT OF APPEALS  
FOR THE FOURTH CIRCUIT**

---

AMERICAN ACADEMY OF PEDIATRICS, et al.,

*Plaintiffs-Appellees,*

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

*Defendants- Appellants,*

E-LIQUIDS MANUFACTURING STANDARDS ASSOCIATIONS, et al.,

*Intervenors-Appellants,*

CIGAR ASSOCIATION OF AMERICA, et al.,

*Appellants.*

---

Appeals from the United States District Court  
for the District of Maryland  
No. 8:18-cv-883 (Grimm, J.)

---

**BRIEF OF *AMICUS CURIAE* MICHAEL SIEGEL, M.D., M.P.H.  
in support of Intervenors-Appellants American E-Liquid  
Manufacturing Standards Association et al.**

---

SANDBERG PHOENIX & VON GONTARD, P.C.

Keith D. Price, #5543278

Andrew D. Ryan, #45924MO

Timothy C. Sansone, #47876MO

Zachary S. Merkle, #68258MO

600 Washington Avenue — 15th Floor

St. Louis, MO 63101-1313

314-231-3332 | 314-241-7604 (Fax)

kprice@sandbergphoenix.com

aryan@sandbergphoenix.com

tsansone@sandbergphoenix.com

zmerkle@sandbergphoenix.com

*Counsel for Michael Siegel, M.D., M.P.H.*

## TABLE OF CONTENTS

<b>Table of Contents</b> .....	<b>i</b>
<b>Table of Authorities</b> .....	<b>ii</b>
<b>Introduction and Statement of Interest of Amicus Curiae</b> .....	<b>1</b>
<b>Argument</b> .....	<b>3</b>
I. Using electronic cigarettes is safer than smoking and switching from smoking to e-cigarettes improves both respiratory and cardiovascular health.....	3
II. Electronic cigarettes are effective in promoting smoking cessation and they are more effective than nicotine replacement therapy, considered the gold standard.....	8
III. The FDA has established that cartridge-based pod systems, not open systems typically sold by vape shops, are the main cause of youth e-cigarette use. ....	11
IV. The PMTA requirements do not immediately remove products from the market and thus are not designed to address a “public health emergency.” .....	12
V. Immediate implementation of PMTA requirements will result in an immediate and substantial increase in cigarette consumption. ....	13
<b>Conclusion</b> .....	<b>15</b>
<b>Certificate of Compliance</b> .....	<b>17</b>
<b>Certificate of Service</b> .....	<b>17</b>

## TABLE OF AUTHORITIES

### Cases

<i>Am. Acad. of Pediatrics v. Food &amp; Drug Admin.</i> , <u>399 F. Supp. 3d 479</u> (D. Md. 2019) .....	15
---	----

### Other Authorities

Charles D. Baker, Governor of Massachusetts, <i>Governor’s Declaration of Emergency</i> (Sept. 24, 2019) .....	13
Davide Campagna, et al., <i>Changes in breathomics in a 1-year randomized smoking cessation trial of electronic cigarettes</i> , <i>European J. of Clinical Investigation</i> , Vol. 46(8) (2016) .....	5
<i>Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization — Guidance for Industry</i> , U.S. Food and Drug Administration (Jan. 2020) .....	11
Fabio Cibella et al., <i>Lung function and respiratory symptoms in a randomized smoking cessation trial of electronic cigarettes</i> . <i>Clinical Science</i> , Vol. 130(21) (2016).....	4
Gideon St. Helen et al., <i>Comparison of systemic exposure to toxic and/or carcinogenic volatile organic compounds (VOC) during vaping, smoking, and abstention</i> , <i>Cancer Prevention Research</i> (2019) .....	7
Jacob George, et al., <i>Cardiovascular effects of switching from tobacco cigarettes to electronic cigarettes</i> , <i>J. American College of Cardiology</i> , Vol. 74(25) (2019).....	7
Kaitlyn Berry et al., <i>E-cigarette initiation and associated changes in smoking cessation and reduction: The Population Assessment of Tobacco and Health study, 2013-2015</i> , <i>Tobacco Control</i> , Vol. 28 (2019).....	10
Michael Siegel, <i>Sales Data Show that Massachusetts Vaping Product Ban Has Already Caused Severe</i>	

*Harm as Vapers Migrate to Smoking in Large Numbers, The Rest of the Story: Tobacco and Alcohol News Analysis and Commentary (blog) (October 30, 2019)*..... 14

Peter Hajek et al., *A randomized trial of e-cigarettes versus nicotine-replacement therapy*, *New England J. Med.*, Vol. 380(7) (2019) ..... 8

Riccardo Polosa et al., *Blood pressure control in smokers with arterial hypertension who switched to electronic cigarettes*, *Int’l J. Environmental Research & Pub. Health*, Vol. 13(11) (2016) ..... 6

Riccardo Polosa et al., *Evidence for harm reduction in COPD smokers who switch to electronic cigarettes*, *Respiratory Research* Vol. 17:166 (2016) ..... 3

Riccardo Polosa et al., *Health effects in COPD smokers who switch to electronic cigarettes: A retrospective-prospective 3-year follow-up*, *Int’l J. of COPD* Vol. 13 (2018)..... 3

Riccardo Polosa et al., *Persisting long term benefits of smoking abstinence and reduction in asthmatic smokers who have switched to electronic cigarettes*, *Discovery Medicine*, Vol. 21(114) (2016) ..... 4

Riccardo Polosa et al., *The effect of e-cigarette aerosol emissions on respiratory health: A narrative review*, *Expert Rev. of Respiratory Medicine*, Vol. 13(9) (2019)..... 6

Sara Kalkhoran et al., *Electronic cigarette use and cigarette abstinence over 2 years among U.S. smokers in the Population Assessment of Tobacco and Health study*, *Nicotine & Tobacco Research* (2019) ..... 10

Yue-Lin Zhuang et al., *Long-term e-cigarette use and smoking cessation: A longitudinal study with US population*, *Tobacco Control*, Vol. 25 (2016)..... 9

## **INTRODUCTION AND STATEMENT OF INTEREST OF AMICUS CURIAE**

Michael Siegel, MD, MPH, is a physician and a professor in the Department of Community Health Sciences at the Boston University School of Public Health. For the past 32 years, he has been a tobacco control researcher and anti-tobacco advocate. He played a major role in advocating across the nation for 100% smoke-free bar and restaurant regulations. Dr. Siegel has testified as an expert witness for plaintiffs in eight different lawsuits against the tobacco industry, including the Engle case, which resulted in an unprecedented \$145 billion verdict against the cigarette companies. He has been recognized as an expert in public health, epidemiology, and tobacco control. He has published nearly 100 peer-reviewed journal articles relating to smoking and tobacco use. He worked for two years as an epidemiologist in the Office on Smoking and Health at the Centers for Disease Control and Prevention (CDC). He has conducted research on electronic cigarettes and has published five peer-reviewed articles in this area.

In short, Dr. Siegel is a long-time, committed anti-tobacco researcher and advocate who has had a career-long interest in reducing the public-health burden of tobacco-related morbidity and mortality.

For this reason, he has a strong interest in the federal regulation of electronic cigarettes and tobacco products.

As required by Federal Rule of Appellate Procedure 29(a)(4)(E), no party's counsel has authored any part of this brief nor has contributed money that was intended to fund preparing or submitting the brief.

Further, no one — other than Siegel and counsel — have contributed money intended to fund preparing or submitting the brief.

## ARGUMENT

### **I. Using electronic cigarettes is safer than smoking and switching from smoking to e-cigarettes improves both respiratory and cardiovascular health.**

Polosa et al. conducted a retrospective chart review of 48 patients with chronic obstructive pulmonary disease (“COPD”).<sup>1</sup> They compared the respiratory health of patients who switched from smoking to e-cigarettes to those who continued smoking, following the patients for a total of two years.<sup>2</sup> Smokers who switched to e-cigarettes experienced a significant reduction in COPD exacerbations, an improvement in respiratory symptoms, and an increase in exercise tolerance, while there was no change among smokers who continued to smoke.<sup>3</sup> Prospective follow-up of the same patients for another 12 months detected significant further improvement in the respiratory health of COPD smokers who had switched to e-cigarettes.<sup>4</sup> In another study,

---

<sup>1</sup> Riccardo Polosa et al., *Evidence for harm reduction in COPD smokers who switch to electronic cigarettes*, *Respiratory Research* Vol. 17:166, p. 3 (2016),

[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5162097/pdf/12931\\_2016\\_Article\\_481.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5162097/pdf/12931_2016_Article_481.pdf).

<sup>2</sup> *Id.* at p. 1.

<sup>3</sup> *Id.* at pp. 3–8.

<sup>4</sup> Riccardo Polosa et al., *Health effects in COPD smokers who switch to electronic cigarettes: A retrospective-prospective 3-year follow-up*, *Int’l J. of COPD* Vol. 13, 2533 (2018),

Polosa et al. demonstrated a significant improvement in both subjective respiratory symptoms and objective measures of lung function among smokers with asthma who switched completely to e-cigarettes.<sup>5</sup>

Cibella et al. conducted a randomized clinical trial of e-cigarettes for smoking cessation.<sup>6</sup> Among smokers who switched completely to e-cigarettes, there was a steady improvement in small-airways lung function over one year of follow-up, as measured by the FEF<sub>25-75%</sub>. FEF<sub>25-75%</sub>, or forced expiratory flow, is a measure of small airways resistance in the lungs. The higher levels of forced expiratory volume observed in smokers who switch to e-cigarettes is direct, objective evidence that switching from smoking to vaping improves the respiratory health of smokers. There was also an improvement in

---

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6113943/pdf/copd-13-2533.pdf>.

<sup>5</sup> Riccardo Polosa et al., *Persisting long term benefits of smoking abstinence and reduction in asthmatic smokers who have switched to electronic cigarettes*, *Discovery Medicine*, Vol. 21(114), pp. 99–108 (2016), full text available at

<http://www.discoverymedicine.com/Riccardo-Polosa/2016/02/persisting-long-term-benefits-of-smoking-abstinence-and-reduction-in-asthmatic-smokers-who-have-switched-to-electronic-cigarettes/>.

<sup>6</sup> Fabio Cibella et al., *Lung function and respiratory symptoms in a randomized smoking cessation trial of electronic cigarettes*. *Clinical Science*, Vol. 130(21), pp. 1929–1937 (2016), <https://doi.org/10.1042/CS20160268>.

subjective respiratory symptoms, which correlated with the increased small airways function. The authors concluded that: “Normalization of peripheral airways function was associated with improvement in respiratory symptoms, adding to the notion that abstaining from smoking can reverse tobacco harm in the lung.”<sup>7</sup>

In further testing of these patients, Campagna et al. demonstrated that smokers who switched completely to e-cigarettes experienced significant reductions in airways obstruction, as measured by exhaled nitric oxide.<sup>8</sup> They conclude that: “Smokers invited to switch to electronic cigarettes who completely abstained from smoking showed steady progressive improvements in their exhaled breath measurements and symptom scores. FeNo and eCO normalization is highly supportive of improved respiratory health outcomes and adds to the notion that quitting from tobacco smoking can reverse harm in the lung.”<sup>9</sup>

---

<sup>7</sup> *Id.*; see also the quote in the abstract at <https://doi.org/10.1042/CS20160268>.

<sup>8</sup> Davide Campagna, et al., *Changes in breathomics in a 1-year randomized smoking cessation trial of electronic cigarettes*, *European J. of Clinical Investigation*, Vol. 46(8), pp. 698–706 (2016), <https://doi.org/10.1111/eci.12651>.

<sup>9</sup> *Id.*

A 2019 review of the scientific evidence concluded unequivocally that electronic cigarettes are substantially safer than conventional cigarettes in terms of respiratory health effects.<sup>10</sup> The review concluded, “Growing evidence supports the relative safety of EC emission aerosols for the respiratory tract compared to tobacco smoke.”<sup>11</sup>

Not only does switching from smoking to e-cigarette use improve respiratory health, but it improves cardiovascular health as well. Polosa et al. reported that smokers with high blood pressure who switched completely to e-cigarettes experienced significant lowering of both their systolic and diastolic blood pressure and better blood pressure control, while there was no change in patients who continued to smoke.<sup>12</sup>

George et al. reported the results from a clinical trial in which they demonstrated that within just one month, smokers who switched to e-cigarettes experienced a significant improvement in vascular

---

<sup>10</sup> Riccardo Polosa et al., *The effect of e-cigarette aerosol emissions on respiratory health: A narrative review*, *Expert Rev. of Respiratory Medicine*, Vol. 13(9), pp. 899–915 (2019), [https://www.nysenate.gov/sites/default/files/st\\_polosa\\_vaping\\_2019\\_0.pdf](https://www.nysenate.gov/sites/default/files/st_polosa_vaping_2019_0.pdf).

<sup>11</sup> *Id.* at p. 1.

<sup>12</sup> Riccardo Polosa et al., *Blood pressure control in smokers with arterial hypertension who switched to electronic cigarettes*, *Int'l J. Environmental Research & Pub. Health*, Vol. 13(11), p. 1123 (2016), <https://www.mdpi.com/1660-4601/13/11/1123/pdf>.

function.<sup>13</sup> The authors conclude that “there is an early benefit to vascular function from switching from TC [tobacco cigarettes] to EC [e-cigarettes].”<sup>14</sup>

Most recently, St. Helen et al. confirmed that there are substantial reductions in exposure to a large number of volatile organic compounds (VOC) when smokers switch to electronic cigarettes, prompting them to conclude that “E-cigarettes expose users to lower levels of toxic VOCs compared with cigarette smoking, supporting their harm reduction potential among smokers.”<sup>15</sup>

To a reasonable degree of scientific certainty, there is no question that e-cigarettes are much safer than conventional cigarettes and that switching from smoking to e-cigarettes results in a substantial improvement in both respiratory and cardiovascular health.

---

<sup>13</sup> Jacob George, et al., *Cardiovascular effects of switching from tobacco cigarettes to electronic cigarettes*, J. American College of Cardiology, Vol. 74(25), pp. 3112–3120 (2019),

<http://www.onlinejacc.org/content/accj/74/25/3112.full.pdf>.

<sup>14</sup> *Id.* at p. 3116.

<sup>15</sup> Gideon St. Helen et al., *Comparison of systemic exposure to toxic and/or carcinogenic volatile organic compounds (VOC) during vaping, smoking, and abstention*, Cancer Prevention Research (2019); see also the Abstract at

<https://cancerpreventionresearch.aacrjournals.org/content/early/2020/01/10/1940-6207.CAPR-19-0356.full-text.pdf>.

**II. Electronic cigarettes are effective in promoting smoking cessation and they are more effective than nicotine replacement therapy, considered the gold standard.**

The most rigorous study to date is a randomized clinical trial of electronic cigarettes compared to nicotine replacement therapy (NRT) for smoking cessation among 886 adult smokers in the UK.<sup>16</sup> The results, which were reported in the *New England Journal of Medicine*, revealed that e-cigarettes were significantly more effective for smoking cessation than NRT.<sup>17</sup> The rate of sustained abstinence from smoking for one year was 18.0% in the e-cigarette group compared to 9.9% in the NRT group.<sup>18</sup> The study concludes that e-cigarettes were more effective than NRT for smoking cessation.<sup>19</sup>

Based on data from the National Health Interview Survey, there are approximately 3 million adult ex-smokers in the United States who

---

<sup>16</sup> Peter Hajek et al., *A randomized trial of e-cigarettes versus nicotine-replacement therapy*, *New England J. Med.*, Vol. 380(7), pp. 629–637 (2019), [http://eprints.whiterose.ac.uk/142483/1/NEJM\\_TEC\\_Hajek\\_et\\_al\\_2019.pdf](http://eprints.whiterose.ac.uk/142483/1/NEJM_TEC_Hajek_et_al_2019.pdf).

<sup>17</sup> *Id.* at p. 1.

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

quit smoking using e-cigarettes and are currently relying upon the availability of e-cigarettes to keep them from returning to smoking.<sup>20</sup>

Not only do clinical-trial and population-based data demonstrate that e-cigarettes are effective for smoking cessation, but survey data confirm these findings. For example, Zhuang et al. reported that among smokers who switched to e-cigarettes and continued to use e-cigarettes two years later, 42% were able to quit smoking completely, compared to just 16% of smokers who did not try e-cigarettes.<sup>21</sup>

In the largest, multi-wave, longitudinal survey of smokers ever conducted in the U.S. (the Population Assessment of Tobacco and Health [PATH] study), Kalkhoran et al. reported that smokers who switched to daily e-cigarette use were almost twice as likely to quit

---

<sup>20</sup> Brad Rodu, *CDC Data: Vaping Increased in 2018, Particularly Among Former Smokers*, Tobacco Truth (blog) (Jul. 6, 2019), <https://rodutobaccotruth.blogspot.com/2019/07/cdc-data-vaping-increased-in-2018.html>; see also Brad Rodu, D.D.S., Univ. of Louisville School of Medicine (last accessed Jan. 29, 2020), <http://louisville.edu/medicine/research/cancer/bkrodu01>.

<sup>21</sup> Yue-Lin Zhuang et al., *Long-term e-cigarette use and smoking cessation: A longitudinal study with US population*, Tobacco Control, Vol. 25, pp. i90–i95 (2016), [https://tobaccocontrol.bmj.com/content/tobaccocontrol/25/Suppl\\_1/i90.full.pdf](https://tobaccocontrol.bmj.com/content/tobaccocontrol/25/Suppl_1/i90.full.pdf).

smoking as smokers who did not try using e-cigarettes (11% vs. 6%).<sup>22</sup> The authors concluded, “In this nationally representative longitudinal cohort study of US adult cigarette smokers, daily e-cigarette use, compared to no e-cigarette use, was associated with a 77% increased odds of pro-longed cigarette smoking abstinence over the subsequent 2 years.”

Using data from the PATH study, Berry et al. reported that smokers who initiated daily e-cigarette use were nearly 8 times more likely to quit smoking than smokers who did not use e-cigarettes.<sup>23</sup> The authors concluded that “daily e-cigarette initiators were more likely to have quit smoking cigarettes or reduced use compared with non-users.”<sup>24</sup>

To a reasonable degree of scientific certainty, there is no question that e-cigarettes are effective in promoting smoking cessation and that

---

<sup>22</sup> Sara Kalkhoran et al., *Electronic cigarette use and cigarette abstinence over 2 years among U.S. smokers in the Population Assessment of Tobacco and Health study*, *Nicotine & Tobacco Research* (2019), <https://doi.org/10.1093/ntr/ntz114>.

<sup>23</sup> Kaitlyn Berry et al., *E-cigarette initiation and associated changes in smoking cessation and reduction: The Population Assessment of Tobacco and Health study, 2013-2015*, *Tobacco Control*, Vol. 28, pp. 42–49 (2019),

<https://tobaccocontrol.bmj.com/content/tobaccocontrol/28/1/42.full.pdf>.

<sup>24</sup> *Id.*

they are in fact more effective than nicotine replacement therapy, which is considered the gold standard. The best estimate is that there are 3 million adult ex-smokers in the United States who completely quit smoking using e-cigarettes and are currently relying on vaping products to keep them from returning to smoking.

**III. The FDA has established that cartridge-based pod systems, not open systems typically sold by vape shops, are the main cause of youth e-cigarette use.**

The FDA has concluded that what is driving youth use of electronic cigarettes is not the open systems that are typically sold in vape shops but small, sleek, pod- or cartridge-based devices sold at convenience stores and gas stations.<sup>25</sup> These products often contain high levels of nicotine as well as nicotine salt formations that enhance the delivery of nicotine into the blood, simulating the pattern of a real tobacco cigarette. The FDA concluded that “data from the 2019 NYTS also indicate that youth overwhelmingly prefer cartridge-based ENDS products” and that “most youth who were current e-cigarette users

---

<sup>25</sup> *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization — Guidance for Industry*, U.S. Food and Drug Administration (Jan. 2020), <https://www.fda.gov/media/133880/download>.

reported a cartridge-based e-cigarette as their usual brand.”<sup>26</sup> Clearly, the current crisis of youth e-cigarette use was caused not by open system vaping products, but by pod-based systems like JUUL, which contain very high nicotine levels and a salt-based nicotine formulation.

**IV. The PMTA requirements do not immediately remove products from the market and thus are not designed to address a “public health emergency.”**

It is important to recognize that the PMTA requirements do not directly remove any products from the market. They only result in the immediate removal of products that do not submit a PMTA application by the deadline. It is highly likely that JUUL will submit an application by the May 2020 deadline, thus allowing its products to remain on the market. Thus, the remedy imposed by the district court will not directly address the purported “public health emergency” because it will not immediately remove JUUL—the primary cause of the youth vaping addiction crisis—from the market. The implementation of PMTA requirements was never intended as a response to any emergent crisis, but instead is a gradual process to ensure the long-term maximization of the public health value of e-cigarette products on the market. The use

---

<sup>26</sup> *Id.* at pp. 15–16.

of the PMTA process to address a “public health emergency” is inappropriate.

**V. Immediate implementation of PMTA requirements will result in an immediate and substantial increase in cigarette consumption.**

We do not need to speculate to understand the likely impact of the broad and immediate enforcement of the PMTA requirements. In Massachusetts, the emergency ban on the sale of electronic cigarettes, which was implemented on September 25, 2019, provides an opportunity to assess the impact on the public’s health when a large number of e-cigarette products are abruptly removed from the shelves of vape shops and other retail outlets.<sup>27</sup> “Sales data reported by PiperJaffray for the four weeks ending October 20 (when the Massachusetts emergency ban was in effect for 25 of the 28 days) and the four previous weeks (mostly before the ban went into effect) were compared to sales data for the previous year. The PiperJaffray analysis revealed that there has been a substantial shift from vaping to smoking in the state,” indicating that “ex-smokers in Massachusetts who were

---

<sup>27</sup> Charles D. Baker, Governor of Massachusetts, *Governor’s Declaration of Emergency* (Sept. 24, 2019), <https://www.mass.gov/files/documents/2019/09/24/Governors-Declaration-of-Emergency.pdf>.

reliant on e-cigarettes to stay smoke-free are now returning to smoking in large numbers.”<sup>28</sup>

Since abrupt implementation of the PMTA requirement will undoubtedly result in the removal of literally thousands of open-system electronic cigarette brands from the market—brands which are relied upon by more than three million ex-smokers to stay off of cigarettes—it is likely that implementation of the PMTA requirement will result in an immediate and substantial increase in cigarette consumption.

The FDA has acknowledged as much. The district court explained that:

Also, Defendants, along with the amici that filed a joint brief in support of Defendants' position ... contend that the four-month timeframe for applications “would threaten to abruptly clear the market of e-cigarette products, creating a ‘genuine risk’ that adult former smokers addicted to nicotine would ‘migrat[e] from potentially less harmful ENDS products [i.e., e-cigarettes] back to combustible tobacco products.’” ... Aware of these potential public health implications in not only the presence of e-cigarettes, but also in what

---

<sup>28</sup> Michael Siegel, *Sales Data Show that Massachusetts Vaping Product Ban Has Already Caused Severe Harm as Vapers Migrate to Smoking in Large Numbers*, The Rest of the Story: Tobacco and Alcohol News Analysis and Commentary (blog) (October 30, 2019), <http://tobaccoanalysis.blogspot.com/2019/10/sales-data-show-that-massachuetts.html>.

could be a precipitous absence, Defendants have carefully calibrated a plan to deal with nicotine addiction throughout the public health sector. Their goal of not driving e-cigarette products out of the market appears to be part of a broader attack on tobacco by encouraging the availability of potentially less addictive products.

*Am. Acad. of Pediatrics v. Food & Drug Admin.*, 399 F. Supp. 3d 479, 484 (D. Md. 2019) (internal citation omitted by ellipses). As the district court acknowledges, there is a need to balance the government's interest in addressing the problem of youth e-cigarette use and its interest in keeping e-cigarette products available as an off-ramp for cigarette smokers. However, the imposed remedy performs no balancing act, as it completely ignores the health of millions of adults who are potentially at serious risk from tobacco-related diseases and who are currently benefiting from and could in the future benefit immensely from the availability of electronic cigarettes.

## CONCLUSION

Based on the above evidence, Dr. Siegel concludes that the remedy imposed by the district court—enforcement of the PMTA requirement in May 2020—will have severely damaging public-health effects. It will lead to an increase in adult cigarette consumption while offering no immediate public health benefits. There are options available to the

FDA — such as more narrowly regulating the cartridge-based products with high nicotine levels — that could more effectively address the problem of youth e-cigarette use while avoiding unintended negative health consequences for adult smokers and ex-smokers.

SANDBERG PHOENIX & VON GONTARD P.C.

*/s/ Keith D. Price*

---

Keith D. Price, #5543278

Andrew D. Ryan, #45924MO

Timothy C. Sansone, #47876MO

Zachary S. Merkle, #68258MO

600 Washington Avenue - 15th Floor

St. Louis, MO 63101-1313

314-231-3332

314-241-7604 (Fax)

kprice@sandbergphoenix.com

aryan@sandbergphoenix.com

tsansone@sandbergphoenix.com

zmerkle@sandbergphoenix.com

*Counsel for Michael Siegel, M.D., M.P.H.*

