

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

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NICOPURE LABS, LLC, <i>ET AL.</i> , ) )	
) )	
<b>Plaintiff,</b> ) )	
) )	
v. ) )	<b>Civil No. 1:16-cv-0878-ABJ</b>
) )	
<b>U.S. FOOD AND DRUG ADMIN., <i>ET AL.</i>,</b> ) )	
) )	
<b>Defendants.</b> ) )	
_____) )	

**PROPOSED BRIEF *AMICUS CURIAE* OF THE  
VAPE A VET PROJECT IN SUPPORT OF THE PLAINTIFFS**

Eric R. Stanco  
(D.C. Bar No. 555538)  
Stanco & Robinson LLP  
2390 Tamiami Trail North  
Suite 216  
Naples, FL 34103  
(239) 263-7755  
(239) 263-8955 (facsimile)  
[erstanco@suretylaw.com](mailto:erstanco@suretylaw.com)  
Counsel for *Amicus Curiae*,  
The Vape A Vet Project

Robert Dunaway  
Law Offices of Robert Dunaway  
4350 East Camelback Road  
Phoenix, AZ 85018  
(602) 468-5751  
(602) 468-1814 (facsimile)  
[dunawaylegal@gmail.com](mailto:dunawaylegal@gmail.com)  
On Brief

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Pursuant to the Court's Order of June 28, 2016, the Vape A Vet Project ("Project") submits this proposed brief as *amicus curiae* in support of Nicopure Labs LLC, *et al.*<sup>1</sup>

## II. STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Project is a 501(c)3 charity founded in 2013 in Phoenix, Arizona. The FDA exceeded its authority in promulgating the Deeming Rule and also ignored or wrongly viewed the considerable evidence supporting the use of electronic nicotine delivery systems ("ENDS"), more commonly known as electronic cigarettes, to combat tobacco use not only in the general population but in the crucial demographic of our active duty service members and veterans.

Veterans and active duty personnel have significantly higher rates of smoking addiction than the general U.S. population, and the rates are even higher for military service members that have been deployed into conflict situations. The Centers for Disease Control and Prevention ("CDC") reported in 2011 that 24% of all active-duty military personnel were currently smoking cigarettes compared with 19% of civilians, and male veterans aged 25–64 years were more likely than non-veterans to still smoke by a margin of 29% to 24%. Tobacco addiction is a troubling health issue for the country, but it is an even bigger problem for the military given its impact on active-duty combat readiness and the later costs of smoking related diseases among veterans.

The Project is the only organization addressing active-duty and veterans' tobacco smoking addiction by promoting a healthier alternative. The Project provides free of charge an electronic cigarette "starter kit" and, subsequently, additional supplies to service members and veterans otherwise could not afford them. In the brief time since its inception, the Project has

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<sup>1</sup> In addition, pursuant to FRAP 29©, the Project and its attorney authored this Brief; no money or other consideration was received by the Project from a party or its counsel to fund the preparation or submission of this Brief; the drafting of this Brief was not funded by any third person or entity, although CASAA's attorney, at CASAA's expense, conformed the Brief to the requirements of this Court and filed it on the Project's behalf.

been very successful, achieving a spectacular success rate in transitioning members and veterans away from traditional cigarettes of six to eight times that of all other nicotine reduction alternatives (*e.g.* nicotine patches, gum, behavioral modification programs).

### **III. SUMMARY OF ARGUMENT**

The U.S. Food and Drug Administration (“FDA”) recently promulgated a final rule that, *inter alia*, comprehensively regulates ENDS for the first time at the federal level. The regulation was adopted pursuant to the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act. *See* 81 Fed. Reg. 28,973 (May 10, 2016) (“Deeming Rule”). In adopting the Deeming Rule, the FDA failed to consider the effectiveness of ENDS in connection with cigarette smoking reduction and cessation efforts and the importance of those programs to the overall health of active duty military personnel and our veterans. Similarly, the FDA failed to consider the relationship between cigarette smoking and combat and mission readiness relative to the usefulness of ENDS in helping active duty personnel to defeat nicotine addiction or, at least, the effects of cigarette smoking. The FDA also ignored the health advantages of ENDS over cigarettes and their usefulness in the battle against smoking addiction. Moreover, the rule’s virtual ban on distributing free samples to adults undermines the Project’s ability to assist service members and veterans during that critical transition period away from cigarettes and, it is hoped, ultimately to a nicotine free lifestyle.

### **V. ARGUMENT**

#### **A. Military Health Concerns Were Not Considered By The FDA In Adopting The Deeming Rule.**

Clearly the FDA did not take into account military health concerns prior to issuing the Deeming Rule. National security is arguably the first priority of the federal government, and the

negative impact of the Deeming Rule upon military preparedness should have been considered. According to the CDC, in 2014, nearly 17 of every 100 U.S. adults aged 18 years or older - an estimated 40 million Americans - smoked cigarettes. Cigarette smoking is the leading cause of preventable disease and death in the U.S., accounting for one in every five deaths or more than 480,000 deaths every year, and approximately 41,000 deaths in the U.S. each year have been attributed to exposure to secondhand smoke.<sup>2</sup>

These statistics are even more disturbing when reviewing tobacco smoking in the military. In the U.S., cigarette smoking is much more prevalent among active duty service men and women than among the civilian population. In a study conducted from 2007 to 2010, the CDC found that 24% of all active-duty military personnel were smokers, compared with 19% of civilians, and male veterans aged 25 to 64 years were more likely to be current smokers than non-veterans 29% versus 24%.<sup>3</sup> Moreover, the percentage of military personnel that smoke cigarettes is even higher for those that who have served in conflict or combat zones. U.S. troops in Iraq and Afghanistan have been reported to smoke at twice the rate of other Americans, negatively impacting combat and mission readiness in critical conflict zones.<sup>4</sup>

The health costs related to smoking are astronomical. Smoking-related illness in the United States costs more than \$300 billion a year, including nearly \$170 billion in direct adult

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<sup>2</sup> Centers for Disease Control and Prevention, "Quick Stats: Current Smoking Among Men Aged 25-64 Years, by Age Group and Veteran Status-National Health Interview Survey, United States, 2007-2010," *Morbidity and Mortality Weekly Report*, November 16, 2012; 61(45): 929.

<sup>3</sup> *Id.*

<sup>4</sup> Institute of Medicine, "Combating Tobacco in Military and Veteran Populations," Washington: The National Academies Press, 2009; Kirby, A..C., *et al.*, "Smoking In Help-Seeking Veterans With PTSD Returning From Afghanistan And Iraq." *Addict Behav.* 33: 1448-53 (2008).

medical care and \$156 billion in lost productivity. But, the relative financial impact of smoking on the military is even greater. The Pentagon recently reported that tobacco use in the military costs \$846 million annually, including over \$130 million per year in excess recruitment and training costs, as smokers are more likely to be discharged during military training.<sup>5</sup> In addition, a 2000 academic study found a consistent correlation between smoking and suicide, which accounts for 13% of fatalities in the military, as the statistical likelihood of men in the service to commit suicide was found to closely track the number of cigarettes smoked daily.<sup>6</sup>

**B. Smoking Compromises Military Combat and Mission Readiness.**

The FDA apparently also failed to consider the impact of tobacco smoking on troop combat and mission readiness when promulgating the Deeming Rule. Multiple studies by scientists at the U.S. Army Public Health Command (“USAPHC”) have found that cigarette smoking results in increased injury risk and diminished physical performance. The risk of injury was found to be as much as 90 percent higher for smokers than nonsmokers, particularly damage to musculoskeletal tissue that accumulates with repetitive activities such as running as smoking directly impacts the body's ability to repair itself. Smoking also negatively impacts muscle endurance, especially as soldiers get older.<sup>7</sup>

The USAPHC has also determined that smoking effects mission readiness. Soldiers who use tobacco have reduced night vision and mental sharpness. Nicotine decreases oxygenated

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<sup>5</sup> Klesges Robert, C; Haddock, Keith C.; Chang, Cyril F.; *et al.* (2001). "The Association of Smoking and the Cost of Military Training." *Tobacco Control* 10: 43–47.

<sup>6</sup> Miller, Matthew, *et al.* (2000). "Cigarette Smoking and Suicide: A Prospective Study of 300,000 Male Active Duty Army Soldiers," *American Journal of Epidemiology* 151: 1060–63.

<sup>7</sup> C. S. Weaver, Soldiers who smoke have increased injury risk, reduced muscle endurance, U.S. Army Public Health Command (December 15, 2011)



blood flow, resulting in a 30% reduction in night vision for normal eyes and a 50% reduction in soldiers who wear corrective lenses. Smoking also results in increased risk of injury related to extreme heat and cold. Smoking reduces blood flow, so the body is less able to cool and warm the extremities, especially fingers and toes.<sup>8</sup>

Smoking also compromises mission security. In addition to the negative physiological effects, sentries on duty can reveal their positions while lighting a cigarette, and an enemy can track the movement of our soldiers through discarded cigarette butts and packaging materials, as well as from actual cigarette smoke.

The military is well aware of these facts and has introduced programs to discourage cigarette smoking. However, such efforts have been largely ineffective, and, in fact, the military recently reported it missed its own goal to reduce smoking by 10%.<sup>9</sup>

**C. Electronic Cigarettes Are A Healthier Alternative To Tobacco Use And Are A More Effective Aid In Smoking Reduction And Cessation Rates.**

An electronic cigarette is a nicotine replacement system which allows the user to easily transition away from cigarette smoking by duplicating the smoking experience without the harmful side effects. ENDS are cigarette simulation apparatuses which combine the actual act of smoking at adjustable nicotine levels without the combustion of tobacco and inhalation of resulting carcinogens. Instead, ENDS produce nicotine-infused water vapor, providing the physical experience to satisfy the cigarette smoker, but minus the estimated 600 toxic ingredients and 7,000 chemicals produced in cigarette combustion.

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<sup>8</sup> *Id.*

<sup>9</sup> S. R. Arvey, R. E. Malone, "Advance and Retreat: Tobacco Control Policy in the U.S. Military," *Military Medicine* 173: 985-991 (October 2008).

ENDS are relatively new having only been introduced to the market in a large way in the past 10 years. As a result, there has been a shortage of reliable scientific data regarding the utility of electronic cigarettes in cigarette smoking reduction and cessation efforts. However, recent independent scientific studies sponsored by groups outside the tobacco and pharmaceutical industries have found ENDS to be a very effective smoking reduction and cessation tool. Most recently and notably, in April, 2016, the Royal College of Physicians (“RCP”) – the pre-eminent physician training and accreditation organization in the United Kingdom – released a statement recommending that ENDS be offered to cigarette smokers in an effort to encourage quitting. Indeed, the RCP concluded that electronic cigarettes are safer than conventional cigarettes and stated that there is “resounding evidence” electronic cigarettes are effective in helping tobacco smokers to quit.<sup>10</sup>

Similar endorsements have been made by many other independent scientific study and commentary groups. Researchers from the U.K. Center for Tobacco and Alcohol Studies and the University of Geneva’s Institute of Social and Preventive Medicine have both concluded that ENDS are effective aids in reducing or eliminating tobacco use.<sup>11</sup> The British government’s drug regulatory authority has approved an e-cigarette as a quit-smoking medicine.<sup>12</sup>

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<sup>10</sup> Royal College of Physicians. *Nicotine without smoke: Tobacco harm reduction*. London: RCP (April 2016).

<sup>11</sup> L. Brose, T. Partos, S. Hitchman, A. McNeill, Support for e-cigarette policies: a survey of smokers and ex-smokers in Great Britain, *Tobacco Control* (June 2016); J. Etter, Chris Bullen, Electronic cigarette: users profile, utilization, satisfaction and perceived efficacy, *Addiction* 106:11 (2011).

<sup>12</sup> A. McNeill, L. S. Brose, R. Calder, S. C. Hitchman, P. Hajek, H. McRobbie, “E-cigarettes: An Evidence Update,” Report commissioned by Public Health England (August 2015).

A recent survey conducted by the American Journal of Preventative Medicine reported that 31% of the respondents who used electronic cigarettes – many of whom had been long term smokers who had tried to quit unsuccessfully before – were still abstaining from tobacco cigarettes six months later, a startling success rate. Even more impressive, 34.3 % of those who had stayed off tobacco cigarettes for six months had stopped using any nicotine product, including electronic cigarettes, by that point, and the respondents that were former heavy smokers and using ENDS more than 20 times per day had a cessation success rate of 70%!<sup>13</sup>

These astounding results stand in stark comparison to other nicotine replacement therapies. For example, a recent study on the effectiveness of nicotine patches reported that only 8.2% had abstained from cigarette smoking after 24 weeks.<sup>14</sup> A similar study of smokers using nicotine gum found that only 7.7% of the prescribed gum group and 8.4% using over the counter gum were not smoking at six months.<sup>15</sup> These results are typical of all nicotine replacement therapies except ENDS.<sup>16</sup> Of course, ENDS users' dramatically better success rate is likely a result of the difference in delivery systems of electronic cigarettes and other therapies. ENDS more effectively satisfy a smoker's craving by both delivering nicotine as rapidly and consistently as a tobacco cigarette, while also duplicating the habitual inhalation of combustible

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<sup>13</sup> M. B. Siegel, K. L. Tanwar, K. S. Wood, "Electronic Cigarettes As A Smoking-Cessation Tool," *Results From An Online Survey* 40:4 (April 2011).

<sup>14</sup> H. R. Alpert, *et al.*, "A Prospective Cohort Study Challenging The Effectiveness Of Population-Based Medical Intervention For Smoking Cessation," *Tobacco Control* (2011)

<sup>15</sup> S. Shiffman, C.N. Rolf, S.J. Hellebusch, *et al.*, "Real-World Efficacy of Prescription and Over-the-counter Nicotine Replacement Therapy," *Addiction* (May 2002)

<sup>16</sup> L. Stead, R. Perera, *et al.*, "Nicotine Replacement Therapy for Smoking Cessation." *Cochrane Database of Systematic Reviews* 2012, Issue 11. Art. No.: CD000146 (November 2012)

cigarette smoking, and, as ENDS technology improves makers will likely develop even more effective ways to satisfy and transition the tobacco smoker away from traditional cigarettes.

**D. The Deeming Rule's Essential Ban On Distribution Of Free Samples Stymies The Anti-Smoking Efforts Of Organizations Like The Project.**

The Deeming Rule virtually bans the distribution of free ENDS product samples, which will end the Project's ability to pursue its charitable mission. The Project's success has been based upon its ability to provide free starter kits and replenishment packages to active-duty personnel and veterans trying to quit tobacco smoking. Many veterans are low income earners and could not afford ENDS products without the starter kit and supplies the Project provides. In only three years, the Project has shipped over 7,500 starter and care packages, making them available free to more than an estimated 16,000 service members. Accordingly, based upon the Project's 60% success rate, to date it has helped more than 10,000 active duty and veteran service members to quit smoking, and it expects to expand the program and increase the number of members it is able to help each year. Of course, however, none of that will come to pass if the FDA's ban on the distribution of free ENDS products is permitted to stand.

**VI. CONCLUSION**

For the foregoing reasons, the Deeming Rule should be rejected as unsound and unlawful and contrary to public policy.

Respectfully submitted:

/s/ Eric R. Stanco

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Eric R. Stanco  
Counsel for the Vape A Vet Project