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### **ABSTRACT**

Electronic Nicotine Delivery Systems ("ENDS") were introduced in India in the late 2000s and were getting popular, especially among school going youth and young adults. ENDS were widely promoted and marketed as harm reduction products or safer alternatives to cigarette smoking. Multinational tobacco giants soon gained complete control over the production and marketing of ENDS in an effort to expand the global tobacco industry. The unregulated sale of nicotine, an addictive and psychoactive carcinogen, not only posed a general threat related to the quality and safety standards for ENDS, but also undermined the progress made in tobacco control by renormalising smoking, appealing to the youth and creating a whole new cadre of dual users (i.e. smokers who use ENDS as the gateway to smoking and vice versa). Moreover, with every passing day scientific research has further pointed to the greater public health risks of ENDS use per se including heart disease, lung diseases, cancer etc. ENDS use has become a youth epidemic in the United States of America with 60 reported deaths from ENDS related lung injury and nearly 2700 others suffering from it. With this background, the Government of India, which had been making piecemeal efforts to curb ENDS in the previous couple of years, finally imposed a comprehensive ban on the production, manufacture, import, export, transport, sale, distribution, storage and advertisement of ENDS in the country. This paper looks at the health and other risks of ENDS use and the legal and public health implications of the recent legislation on its ban in India.

### I. INTRODUCTION

Nicotine is one of the ingredients in tobacco.<sup>1</sup> Like cocaine and morphine, nicotine is a powerful drug that speeds up the brain's central nervous system and triggers the release of dopamine that alters one's mood, appetite and alertness. But for nicotine, there is little doubt that people would be inclined to smoke or use tobacco.<sup>2</sup> The industry, which denied the fact for decades that tobacco was addictive, always knew that

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<sup>&</sup>lt;sup>1</sup> See Fact sheet on ingredients in tobacco products, World Health Organization, WHO/NMH/PND/15.2, (2014), available at

https://www.who.int/tobacco/industry/product\_regulation/factsheetingredients/en/, last seen 14/02/2020.

<sup>&</sup>lt;sup>2</sup> M.A.H. Russell, *The Smoking Habit and Its Classification*, 212 The Practitioner 791, 793 (1974).

it was nicotine addiction that helps sell their products. Cigarettes today deliver more nicotine and deliver it quicker than ever before.<sup>3</sup>

However, with the rise in global awareness together with action to reduce tobacco use and 180 countries in the world embracing the World Health Organization's Framework Convention on Tobacco Control ("WHO FCTC"), there are countries that have introduced smoking bans in public places, graphic warnings on packaging and other effective tobacco control measures.<sup>4</sup> More and more countries are protecting people from the dangers of tobacco smoke by enacting laws that create smoke-free workplaces and public places. The Supreme Court of India in 2001, directed the central and state governments to ensure that all public places are free from tobacco smoke. The Apex Court observed,

"Fundamental right guaranteed under Article 21 of Constitution of India, inter alia, provides that none shall be deprived of his life without due process of law. Then why a non-smoker should be afflicted by various diseases including lung cancer or of heart, only because he is required to go to public places? Is it not indirectly depriving of his life without any process of law? The answer is obviously - 'yes'. Undisputedly, smoking is injurious to health and may affect the health of smokers but there is no reason that health of passive smokers should also be injuriously affected. In any case, there is no reason to compel non-smokers to be helpless victims of air pollution."

The Parliament enacted the Cigarettes and Other Tobacco Products Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution Act, 2003 ("COTPA") which, under Section 4, completely prohibits smoking in public places.

In 2008, the Ministry of Health and Family Welfare, Government of India ("MoHFW") introduced stronger regulations to curb smoking in public places and imposed stricter ventilation requirements for creating smoking areas.<sup>7</sup> The regulations also designated enforcement officers at

<sup>&</sup>lt;sup>3</sup> This July 4th, Gain Freedom From Tobacco Use, The Centers for Disease Control and Prevention, available at http://www.cdc.gov/features/smokingindependence/, accessed 06/10/2014;

D. Mosbergen, Cigarettes Are More Addictive Than Ever Before, Suggests New Study, Huffington Post (7/12/2014), available at http://www.huffingtonpost.com/2014/01/17/cigarettes-more-addictivestudy\_n\_4618612.html, last seen on 06/10/2014.

<sup>&</sup>lt;sup>4</sup> M. Hefler, World: Gandhi's legacy and a Tobacco-Free World, Tobacco Control Blog, https://blogs.bmj.com/tc/2019/10/01/world-gandhis-legacy-and-aavailable tobacco-free-world/, last seen on 04/01/2020.

<sup>&</sup>lt;sup>5</sup> Murli S Deora v. Union of India, (2001) 8 SCC 765.

<sup>&</sup>lt;sup>7</sup> National Tobacco Control Programme, Ministry of Health and Family Welfare, Government of India, available at https://main.mohfw.gov.in/major-programmes/other-nationalhealth-programmes/national-tobacco-control-programme-ntcp, seen on

all public places and made the managers or owners of such public places responsible for keeping the space smoke-free or be liable to pay fine for as many instances of smoking at such public place.

Globally, such laws and regulations presented less and less possibilities for smoking, presented more and more chances for breaking the nicotine dependence and started affecting the sales of the tobacco industry. The industry that had already started testing electronic cigarettes since 1960 as 'reduced harm' or 'socially acceptable' alternatives to conventional cigarettes started its commercial production from late 2010s. Although, the tobacco industry tested and patented alternative non-tobacco nicotine cigarettes British American Tobacco's (BAT) 1960s Ariel cigarette, RJ Reynolds' (RJR) 1980s Premier, RJR's 1990s Eclipse and Philip Morris' (PM's) 1990s/2000s Accord), it was the introduction of modern electronic cigarettes in China as a potential cessation device or an alternative cigarette product that took the tobacco industry by surprise.

To safeguard its business interests, the industry started acquiring all big and small electronic cigarettes producers globally and introducing its own electronic cigarette products. It used its size and financial firepower to take over the electronic cigarettes market and within a couple of years it was the tobacco industry that held the largest market share of the electronic cigarettes market globally.<sup>11</sup> Today electronic cigarettes are sold across the world in several types, names and design as seen in Figure 1 below, including e-cigarettes, "e-cigs," "cigalikes," "e-hookahs," "e-sheesha," "mods," "vape pens," "vapes," "tank systems" and the latest entrant being "JUUL".<sup>12</sup> These are collectively known as electronic nicotine delivery devices ("ENDS").

<sup>16/02/2020</sup>. (Smoking area may be provided only at three places i.e. a restaurant with 30 or more seating capacity, a hotel with 30 or more rooms and an airport.).

<sup>&</sup>lt;sup>8</sup> L.M. Dutra, R. Grana, S.A. Glantz, *Philip Morris research on precursors to the modern e-cigarette since 1990*, 26(2) Tobacco Control 97, (2017), available at https://tobaccocontrol.bmj.com/content/26/e2/e97, last seen on 13/01/2020.

<sup>9</sup> Ibid.

<sup>&</sup>lt;sup>10</sup> See W. Wang, Z. He, N. Feng, Y. Cai, *Electronic cigarette use in China: Awareness, prevalence and regulation*, 17 Tobacco Induced Diseases 1, (2019) available at http://www.tobaccoinduceddiseases.org/Electronic-cigarette-use-in-China-Awareness-prevalence-and-nregulation,105393,0,2.html, last seen on 16/02/2020.

<sup>&</sup>lt;sup>11</sup> C. Abate, *Tobacco Companies Taking Over the E-Cigarette Industry*, Huffpost (27/01/2017), available athttps://www.huffpost.com/entry/tobacco-companies-taking-over-the-ecigarette-industry b 58b48e02e4b0658fc20f98d0, last seen on 22/02/2020.

<sup>&</sup>lt;sup>12</sup> Electronic Cigarettes, Centers for Disease Control and Prevention, available at https://www.cdc.gov/tobacco/basic\_information/e-cigarettes/index.htm, last seen on 14/01/2020; What Do We Know About E-cigarettes?, American Cancer Society, available at https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/e-cigarettes.html, last seen on 14/01/2020.

ENDS generally look like regular cigarettes, cigars, or pipes, while some look like USB flash drives, pens, and other everyday items. ENDS are battery-powered smoking devices, which have cartridges filled with a liquid that usually contains nicotine, flavourings and chemicals.<sup>13</sup> The liquid is heated into a vapor, which the person inhales. Therefore, using ENDS is called "vaping." Despite this common and innocuous nomenclature, some avoid using the term "ENDS", because ENDS emissions are, more accurately, aerosols which also contain "ultra-fine particles, volatile organic compounds, and other toxins."

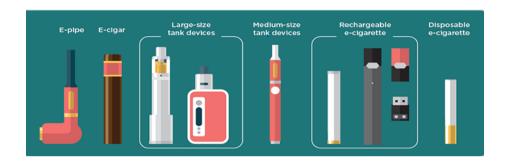


Fig-1: Different varieties of ENDS

Source: Centers for Disease Control and Prevention-USA. Electronic Cigarettes.

Available at: https://www.cdc.gov/tobacco/basic\_information/e-cigarettes/about-e-cigarettes.html

### II. EARLY MARKETING OF ENDS

Initially, the industry itself was not very sure about the strategy to market ENDS to consumers. Some of them started marketing their ENDS as a harm reduction device, some started marketing it as a cessation aid and some as an alternative to traditional cigarettes.<sup>16</sup> The Indian premier tobacco company started selling its own e-cigarette brand in 2014

<sup>&</sup>lt;sup>13</sup> About Electronic Cigarettes, Centre for disease control and Prevention, available at https://www.cdc.gov/tobacco/basic\_information/e-cigarettes/about-e-cigarettes.html, last seen on 16/02/2020.

<sup>&</sup>lt;sup>14</sup> Electronic Cigarettes, Centres for Disease Control and Prevention, available at https://www.cdc.gov/tobacco/basic\_information/e-cigarettes/index.htm, last seen on 14/01/2020;

What Do We Know About E-cigarettes?, American Cancer Society, available at https://www.cancer.org/cancer/cancer-causes/tobacco-and-cancer/e-cigarettes.html, last seen on 14/01/2020.

<sup>&</sup>lt;sup>15</sup> Electronic Smoking Devices and Second hand Aerosol, American Nonsmokers Rights Foundation, available at https://no-smoke.org/electronic-smoking-devices-secondhand-aerosol/ last seen on 19/01/2020.

<sup>&</sup>lt;sup>16</sup> 10 Surprising Facts About E-Cigarettes, Centre on Addiction, available at https://www.centeronaddiction.org/e-cigarettes/about-e-cigarettes/10-surprising-facts-about-e-cigarettes, last seen on 16/02/2020.

promising that it gave the 'pleasure of smoking anytime anywhere'<sup>17</sup> (i.e. including public places, where smoking was otherwise banned under COTPA). Warnings on several of the ENDS products suggested that they were not smoking cessation products (i.e. they only helped in maintaining the nicotine addiction and dependence while promoting dual use among tobacco users).<sup>18</sup>

Instead of marketing ENDS as a cessation device, as several of the initial manufacturers intended, the tobacco industry started to market ENDS as an alternative to traditional cigarettes riding on the reduced harm arguments. In doing so, the industry was also able to divide health and tobacco control professionals into two groups. One group recognized that ENDS have a reduced risk of causing disease and embraced them as a crucial element of tobacco control policy while the other focused on preventing people from beginning to use tobacco products and encouraging people to quit.

### III. MYTHS RELATED TO ENDS

Although the tobacco industry presents ENDS as a part of the solution, <sup>19</sup> in reality it is meant not only to suppress quitting by providing an alternative device to deliver and maintain nicotine addiction among current smokers - most ENDS users are "dual users" who continue to smoke cigarettes - but, more importantly, to recruit a whole new generation that is growing under the protected environment of WHO FCTC into nicotine addiction and eventually cigarette smoking. <sup>20</sup>

Reviews of evidence about reducing smoking (instead of quitting) show that dual users are unlikely to see any health benefits in terms of

<sup>&</sup>lt;sup>17</sup> M. Rao, *Should e-cigarettes be banned in India? Experts are divided,* Scroll.in (11/06/2020), available at https://scroll.in/pulse/810375/can-e-cigarettes-subvert-tobacco-control-measures-in-the-country, last seen on 16/02/2020.

<sup>&</sup>lt;sup>18</sup> See A. Bhatnagar, L.P. Whitsel, M.J. Blaha, et al., New and Emerging Tobacco Products and the Nicotine Endgame: The Role of Robust Regulation and Comprehensive Tobacco Control and Prevention: A Presidential Advisory From the American Heart Association, 139(19) AHA Journals 937, (2019), available at https://www.ahajournals.org/doi/full/10.1161/CIR.00000000000000669, last seen on 16/02/2020.

<sup>&</sup>lt;sup>19</sup> Top scientists warn WHO not to stub out e-cigarettes, Reuters (29/05/2014), available at http://www.reuters.com/article/2014/05/28/health-ecigarettes-idUSL6N0OD3ZE20140528, last seen on 24/10/2014.

<sup>&</sup>lt;sup>20</sup> R. Grana, N. Benowitz, S.A. Glantz, *E-cigarettes: a Scientific Review*, 129(19) Circulation 1972, (2014), available at

https://www.ahajournals.org/doi/10.1161/circulationaha.114.007667, last seen on 28/04/2020; S.A. Glantz, 129 public health and medical authorities from 31 countries write WHO DG Chan urging evidence-based approach to ecigs, Centre for Tobacco Control Research and Education, available at https://tobacco.ucsf.edu/129-public-health-and-medical-authorities-31-countries-write-who-dg-chan-urging-evidence-based-approachecigs# edn23, last seen on 28/04/2020.

cardiovascular disease.<sup>21</sup> Population studies of all smokers consistently show that smokers who use ENDS are *less* likely to stop smoking."<sup>22</sup> The fact that the tobacco industry continues to produce conventional cigarettes is evidence enough of the vicious intentions of the industry in promoting ENDS. All the claims related to ENDS made by the industry, therefore, are either contradicted by available evidence or for which no evidence is currently available.<sup>23</sup>

A White Paper by an expert group constituted by the Indian Council of Medical Research, New Delhi, was released on 31 May 2019.<sup>24</sup> The White Paper provided a telling story of how ENDS are not the products that the tobacco industry wants us to believe they are.

Prof. Simon Chapman from the Sydney University has unequivocally summarized these industry tactics and said,

"Big-Tobacco's five goals are widespread dual use; retarding smoking cessation; resocialising public smoking back into fashion from its forlorn exile outside buildings;

<sup>&</sup>lt;sup>21</sup> Ibid; C. Pisinger, N.S. Godtfredsen, *Is there a health benefit of reduced tobacco consumption? A systematic review*, 9 Nicotine and Tobacco Research 631, (2007), available at https://www.ncbi.nlm.nih.gov/pubmed/17558820, last seen on 15/01/2020.

<sup>&</sup>lt;sup>22</sup> S.E. Adkison, R.J. O'Connor, M. Bansal-Travers, et al., *Electronic Nicotine Delivery Systems: International Tobacco Control Four-Country Survey*, 44 American Journal of Preventive Medicine 207, (2013), available at https://www.ncbi.nlm.nih.gov/pubmed/23415116, last seen on 15/01/2020;

S.A. Glantz, 129 public health and medical authorities from 31 countries write WHO DG Chan urging evidence-based approach to evigs, Centre for Tobacco Control Research and Education, available at https://tobacco.ucsf.edu/129-public-health-and-medical-authorities-31countries-write-who-dg-chan-urging-evidence-based-approach-ecigs#\_edn23, last seen on 28/04/2020; R.A. Grana, L. Popova, P.M. Ling, A longitudinal analysis of electronic cigarette use and smoking cessation, 174 JAMA Internal Medicine 812, (2014), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4122246/, last seen on 28/04/2020; K.A. Vickerman, K.M. Carpenter, T. Altman T et al, Use of electronic cigarettes among state tobacco cessation quitline callers, 15 Nicotine and Tobacco Research 1787, (2013), available at https://www.ncbi.nlm.nih.gov/pubmed/23658395, last seen on 16/01/2020; L. Popova, P.M. Ling, Alternative tobacco product use and smoking cessation: a national study, 103 American Journal of Public Health 923, (2013),available https://www.ncbi.nlm.nih.gov/pubmed/23488521, last seen on 14/01/2020; R. Grana, N. Benowitz, S.A. Glantz, E-cigarettes: a Scientific Review, 129(19) Circulation 1972, (2014), available at https://www.ahajournals.org/doi/10.1161/circulationaha.114.007667, last seen on 15/01/2020.

<sup>&</sup>lt;sup>23</sup> S.A. Glantz, 129 public health and medical authorities from 31 countries write WHO DG Chan urging evidence-based approach to ecigs, Centre for Tobacco Control Research and Education, available at https://tobacco.ucsf.edu/129-public-health-and-medical-authorities-31-countries-write-who-dg-chan-urging-evidence-based-approach-ecigs#\_edn23, last seen on 28/04/2020.

<sup>&</sup>lt;sup>24</sup> Indian Council of Medical Research, *White Paper on Electronic Nicotine Delivery System*, 149(5) Indian Journal of Medical Research 574, (2019), available at http://www.ijmr.org.in/article.asp?issn=0971-

<sup>5916;</sup>year=2019;volume=149;issue=5;spage=574;epage=583;aulast=Indian, last seen on 12/01/2020.

conveying to young, apprehensive would-be smokers that nicotine is a benign drug; and welcoming back lapsed smokers."<sup>25</sup>

Table-1: Myths related to ENDS

|   | Myths related to ENDS   | Reality of ENDS  |  |  |  |
|---|---|--|--|--|--|
| 1 | Safer alternative to traditional cigarettes   | Almost same risk as traditional cigarettes for causing heart attacks, lung diseases and possibly cancer as well. It has created a more vulnerable group of dual users who are unlikely to see any health benefit and are instead exposed to greatest risk of heart attacks.  |  |  |  |
| 2 | Helps in quitting smoking   | The industry itself does not promote ENDS as a cessation product. Studies indicate it might be suppressing cessation by nearly one-third.  |  |  |  |
| 3 | Not meant for minors  | Globally, wherever it was introduced, it became more popular among school going kids and young adults. In the United States, youth prevalence surpassed adult prevalence in 2014. With more than 460 brands and nearly 8000 flavours, marketing of ENDS is primarily targeted to minors. It also acts as a gateway product for minors and teenagers. |  |  |  |
| 4 | Not contrary to the tobacco control/smoke free regulations or the WHO FCTC mandates | It violates provisions of several domestic tobacco control statutes. It is also against the mandate of Article 16(1)(c) of the WHO FCTC which calls for "prohibiting the manufacture and sale of sweets, snacks, toys or any other objects in the form of tobacco products which appeal to minors." Use of   |  |  |  |

<sup>&</sup>lt;sup>25</sup> S. Chapman, *Should electronic cigarettes be as freely available as tobacco cigarettes? No*, The BMJ, available at https://www.bmj.com/content/346/bmj.f3840, last seen on 12/01/2020.

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|   |                           | ENDS in public places renormalizes smoking against the spirit of Article 8 of the WHO FCTC and Section 4 of COTPA.  |  |  |  |
|---|---------------------------|---|--|--|--|
| 5 | Safe and standard product | Several incidents of fire and explosion of ENDS devices have resulted in loss of life and property. Accidental ingestion by kids causing their death is often reported. |  |  |  |

The cigarette companies wanted to manufacture and market ENDS only to protect and prevent the market share of their products from the real competition from any effective cessation product in the market. The best way forward for the industry to ensure this was to takeover, design and market the potential competition product by itself. The story in India was the same as anywhere in the world. These were the same tobacco companies who were producing cigarettes, smokeless tobacco and ENDS products.

Table-2: Tobacco companies market ENDS

|   | Tobacco Company                  | Tobacco<br>products                       | ENDS<br>Product |  |
|---|----------------------------------|---|-----------------|--|
| 1 | ITC Pvt. Ltd.                    | Wills Navy Cut,<br>Gold Flake etc.        | Eon             |  |
| 2 | Godfrey Phillips Pvt.<br>Ltd.    | Red and White,<br>Four Square etc.        | Verge           |  |
| 3 | Trimurti Fragrances Pvt.<br>Ltd. | Shikhar Gutkha,<br>Shikhar Khaini<br>etc. |                 |  |
| 4 | Phillip Morris (ITC's partner)   | Marlboro, Benson<br>& Hedges etc.         | iQOS, JUUL      |  |

| 5 | British<br>Tobacco<br>Phillips' partne | American<br>(Godfrey | · · | Camel | Vype,<br>Glo, Neo | Vuse, |
|---|--|----------------------|-----|-------|-------------------|-------|
|   | Phillips' partne                       | r)                   |     |       |                   |       |

### IV. ADVERSE HEALTH EFFECTS OF ENDS

There are several apparent risks of using ENDS, including constant intake of chemicals such as propylene glycol, vegetable glycerin, polyethylene glycol and nicotine.<sup>26</sup> Nicotine per se is classified as a poison and in light of its adverse impact, its use even as an insecticide has been banned.<sup>27</sup> Nicotine is a highly addictive stimulant which can cause immediate cardiovascular effects such as vasoconstriction, increased heart rate, and increased blood pressure.<sup>28</sup> In the long term, nicotine can lead to endothelial dysfunction, platelet aggregation and other conditions which lead to cardiovascular diseases.<sup>29</sup> While comparing conventional cigarettes and initial verities of ENDS, it was observed that the latter required stronger vacuums (suction) to smoke than conventional cigarettes which could have adverse effect on human health.<sup>30</sup> The vapor from ENDS causes a pro-inflammatory response from human neutrophils which is known to contribute to lung diseases such as chronic obstructive pulmonary disease ("COPD"). It also contains several harmful chemicals, including known carcinogens.<sup>31</sup>

<sup>&</sup>lt;sup>26</sup> A. Trtchounian, M. Williams, P. Talbot, *Conventional and electronic cigarettes (e-cigarettes) have different smoking characteristics*, 12 Nicotine & Tobacco Research 905, (2010), available at https://www.ncbi.nlm.nih.gov/pubmed/20644205, last seen on 13/01/2020.

<sup>&</sup>lt;sup>27</sup> Mishra, P. Chaturvedi, S. Datta et al., *Harmful effects of nicotine*, 36 Indian Journal of Medical and Paediatric Oncology 24, (2015), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4363846/, last seen on 16/02/2020.

<sup>&</sup>lt;sup>28</sup> Nicotine, National Center for Biotechnology Information, available at https://pubchem.ncbi.nlm.nih.gov/compound/Nicotine, last seen on 16/02/2020.

<sup>&</sup>lt;sup>29</sup> A. Bhatnagar, *E-cigarettes and cardiovascular disease risk: evaluation of evidence, policy implications, and recommendations*, 10 Current Cardiovascular Risk Reports, (2016), available at https://link.springer.com/article/10.1007%2Fs12170-016-0505-6, last seen on 14/01/2020;

R.J. Schweitzer, T.A. Wills, D. Behner, *E-cigarette use and indicators of cardiovascular disease risk*, 4 Current Epidemiology Report 248, (2017), available at https://link.springer.com/article/10.1007%2Fs40471-017-0118-8, last seen on 12/01/2020.

<sup>&</sup>lt;sup>30</sup> A. Trtchounian, M. Williams, P. Talbot, *Conventional and Electronic Cigarettes (E-Cigarettes) Have Different Smoking Characteristics*, 12 Nicotine & Tobacco Research 905, (2010) available at https://www.ncbi.nlm.nih.gov/pubmed/20644205, last seen on 13/01/2020.

<sup>&</sup>lt;sup>31</sup> A. Higham, N.J. Rattray, J.A. Dewhurst et al., *Electronic cigarette exposure triggers neutrophil inflammatory responses*, 17 Respiratory Research, (2016), available at https://respiratory-research.biomedcentral.com/articles/10.1186/s12931-016-0368-x, last seen on 14/01/2020; A. Scott, S.T. Lugg, K. Aldridge, et al., *Pro-inflammatory Effects of E-Cigarette* 

Further, nicotine exposure during pregnancy has adverse effects on fetal growth and development, including fetal brain development.<sup>32</sup> Other substances in ENDS cause temporary increase in airway resistance and congestion in the lungs resulting in cough, phlegm, sinus congestion, irritation in the throat, hoarse voice, mouth ulcers, acne, hiccups, sleeplessness, bloating, dizziness, change of smell sensation and taste, headache and heartburn. The Cinnamaldehyde found in ENDS has the potential to impair respiratory immune cell function,<sup>33</sup> and use of ENDS alters the profile of innate defense proteins in airway secretions, inducing similar and unique changes relative to cigarette smoking.<sup>34</sup> Diacetyl found in e-liquids is responsible for bronchiolitis obliterans or popcorn lung and other severe respiratory diseases.<sup>35</sup>

In USA, several ENDS users were hospitalized with severe lung illness starting June 2019. The condition was named as 'e-cigarette, or vaping, product use-associated lung injury' or EVALI by the Centre for Disease Control ("CDC"), Atlanta, Georgia, USA.<sup>36</sup> CDC reported significant lung illness and death (2,668 reported cases and 60 deaths as of January 14, 2020) due to vaping in the USA.<sup>37</sup>

### 1. Harmful to others

The aerosol emitted from ENDS contains fine and ultrafine particles, nicotine and other toxic substances which are harmful for others inhaling

Vapour Condensate on Human Alveolar Macrophages, 73(12) Thorax 1161, (2018), available at https://www.ncbi.nlm.nih.gov/pubmed/30104262, last seen on 14/01/2020.

<sup>&</sup>lt;sup>32</sup> U.S. Department of Health and Human Services, Government of United States of America, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, available at https://ecigarettes.surgeongeneral.gov/documents/2016\_SGR\_Full\_Report\_non-508.pdf, last seen on 16/01/2020.

<sup>&</sup>lt;sup>33</sup> P.W. Clapp, E.A. Pawlak, J. Lackey et al., *Flavored e-cigarette liquids and cinnamaldehyde impair respiratory innate immune cell function*, 313 American Journal of Physiology 278, (2017), available at https://www.ncbi.nlm.nih.gov/pubmed/28495856, last seen on 15/01/2020.

<sup>&</sup>lt;sup>34</sup> B. Reidel, G. Radicioni, P.W. Clapp et al., *E-Cigarette Use Causes a Unique Innate Immune Response in the Lung, Involving Increased Neutrophilic Activation and Altered Mucin Secretion*, 197 American Journal of Respiratory and Critical Care Medicine 492, (2018), available at https://www.ncbi.nlm.nih.gov/pubmed/29053025, last seen on 12/01/2020.

<sup>&</sup>lt;sup>35</sup> J.G. Allen, S.S. Flanigan, M. LeBlanc et al., Flavoring Chemicals in E-Cigarettes: Diacetyl, 2,3-Pentanedione, and Acetoin in a Sample of 51 Products, Including Fruit-, Candy-, and Cocktail-Flavored E-Cigarettes, 124 Environmental Health Perspective 733, (2016), available at https://www.ncbi.nlm.nih.gov/pubmed/26642857, last seen on 12/01/2020.

<sup>&</sup>lt;sup>36</sup> Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping Products, Centres for Disease Control and Prevention, available at https://www.cdc.gov/tobacco/basic\_information/e-cigarettes/severe-lung-disease.html, last seen on 16/02/2020.

<sup>37</sup> Ibid.

these substances.<sup>38</sup> It is also responsible for polluting the indoor air as ENDS use leads to an increase in the concentration of carcinogenic Polycyclic Aromatic Hydrocarbons ("PAHs") in the indoor air by 20%, and aluminium increase by 2.4-fold.<sup>39</sup> In addition, it increases exposure of non-smokers and bystanders to nicotine and a number of toxicants.<sup>40</sup> ENDS can cause toxicity among children due to accidental swallowing of e-cigarette liquids.<sup>41</sup> Defective e-cigarette batteries have also caused fires and explosions, some of which have resulted in serious injuries.<sup>42</sup>

### 2. Effect on youth

Studies suggest that youth in USA who had never smoked conventional cigarettes but who used ENDS were almost twice as likely to have intentions to smoke conventional cigarettes as those who had never used ENDS. According to data from the USA National Youth Tobacco Survey, in 2011, the prevalence of e-cigarette use among high school students was 1.5%, which increased dramatically to 16% by 2015 and to 20.8% in 2018. One of the most commonly sold versions of e-cigarettes in USA is JUUL, which now has more than a 70% share of the

<sup>&</sup>lt;sup>38</sup> S.A. Glantz, D.W. Bareham, *E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications*, 39 Annual Review of Public Health 215, (2018) available at https://www.ncbi.nlm.nih.gov/pubmed/29323609, last seen on 13/01/2020;

Electronic nicotine delivery systems Report by WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Russian Federation, October 13-18, FCTC/COP/6/10 (September, 2014), available at http://apps.who.int/gb/fctc/PDF/cop6/FCTC\_COP6\_10Rev1-en.pdf?ua=1, last seen on 19/01/2020.

<sup>&</sup>lt;sup>39</sup> W. Schober, K. Szendrei, W. Matzenetal. *Use of Electronic Cigarettes (E-Cigarettes) Impairs Indoor Air Quality and Increases FeNO Levels of E-Cigarette Consumers*, 217 International Journal of Hygiene and Environmental Health 62, (2014), available at https://www.ncbi.nlm.nih.gov/pubmed/24373737 last accessed 12-01-2020.

<sup>&</sup>lt;sup>40</sup> Electronic nicotine delivery systems Report by WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Russian Federation, October 13-18, FCTC/COP/6/10 (September, 2014), available at http://apps.who.int/gb/fctc/PDF/cop6/FCTC\_COP6\_10Rev1-en.pdf?ua=1, last seen on 19/01/2020.

<sup>&</sup>lt;sup>41</sup> J. Mielke, *E-cigarette poisoning figures soar as vaping habit spreads across UK*, The Guardian (14/04/2014), available at http://www.theguardian.com/society/2014/apr/14/e-cigarette-poisoning-figures-soar-adults-children, last seen on 12/01/2020.

<sup>&</sup>lt;sup>42</sup> Exploding e-cigarette kills 24-year-old Texas man, BBC (5/02/2019), available at https://www.bbc.com/news/world-us-canada-47136678, last seen on 12/01/2020.

<sup>&</sup>lt;sup>43</sup> R.E. Bunnell, I.T. Agaku, R.A. Arrazola, et al., *Intentions to Smoke Cigarettes Among Never-Smoking US Middle and High School Electronic Cigarette Users: National Youth Tobacco Survey, 2011-2013*,17 Nicotine and Tobacco Research 228, (2015), available at https://www.ncbi.nlm.nih.gov/pubmed/25143298, last seen on 13/01/2020.

<sup>&</sup>lt;sup>44</sup> K.A. Cullen, B.K. Ambrose, A.S. Gentzke, et al., *Notes From the Field: Use of Electronic Cigarettes and Any Tobacco Product Among Middle and High School Students - United States, 2011-2018,* 67 Morbidity & Mortality Weekly Report 1276, (2018), available at https://www.ncbi.nlm.nih.gov/pubmed/30439875, last seen on 15/01/2020.

cartridge-based e-cigarette market in the United States.<sup>45</sup> A typical JUUL cartridge, or "pod," contains about as much nicotine as a pack of 20 regular cigarettes.<sup>46</sup>

In Poland, e-cigarettes were the fourth most common source of nicotine among youth after cigarettes, waterpipes, and snuff.<sup>47</sup> Similar proportions of ENDS use was observed in a study conducted with adolescents in Finland. The study also shows that, among smokers, ENDS use was associated with lower interest in smoking cessation while never smokers were also shown to use e-cigarettes.<sup>48</sup> A study among adolescents in Korea revealed 8.0% of ever-dual users were currently using e-cigarettes and smoking conventional cigarettes as well. The study concluded that those who had made an attempt to quit were more likely to use ENDS but less likely to no longer use cigarettes.<sup>49</sup> Studies have also shown that ENDS use by youth is strongly linked to later use of regular cigarettes and other tobacco products,<sup>50</sup> and using ENDS may play a part in a kid or teenager wanting to experiment with other, conventional tobacco products.<sup>51</sup>

Studies from across the globe suggest that the factors associated with ENDS use and sources for ENDS appear similar to those for conventional cigarettes among adolescents.<sup>52</sup> Peers and online sales remain the key sources of acquisition of the products, while internet, social networking sites and youth magazines were reported for advertising

<sup>&</sup>lt;sup>45</sup> B.A. King, D.G. Gammon, K.L. Marynak et al., Electronic Cigarette Sales in the United States, 2013-2017, 320(13) JAMA 1379, (2018), available at https://jamanetwork.com/journals/jama/fullarticle/2705175, last seen on 18/01/2020.

<sup>&</sup>lt;sup>46</sup> J.G. Willett, M. Bennett, E.C. Hair, et al., Recognition, use and perceptions of JUUL among youth and young adults, 28 Tobacco Control 115, (2019), available at https://tobaccocontrol.bmj.com/content/28/1/115, last seen on 15/01/2020.

<sup>&</sup>lt;sup>47</sup> Electronic Cigarette Use Among Teenagers and Young Adults in Poland, 130 Pediatrics 879, (2012), available at https://www.ncbi.nlm.nih.gov/pubmed/22987874, last seen on 15/01/2020.

<sup>&</sup>lt;sup>48</sup> J.M. Kinnunen, H. Ollila, El-Amin et al., *Awareness and determinants of electronic cigarette use among Finnish adolescents in 2013: a population-based study*, 24 Tobacco Control 264, (2015), available at https://tobaccocontrol.bmj.com/content/24/e4/e264, last seen on 13/01/2020.

<sup>&</sup>lt;sup>49</sup> S. Lee, R.A. Grana, S.A. Glantz, Electronic Cigarette Use Among Korean Adolescents: A Cross-Sectional Study of Market Penetration, Dual Use, and Relationship to Quit Attempts and Former Smoking, 54(6) Journal for Adolescent Health 684, (2014), available at https://www.ncbi.nlm.nih.gov/pubmed/24274973, last seen on 14/01/2020.

<sup>50</sup> U.S. Department of Health and Human Services, Government of United States of America, E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General, available at https://e-

cigarettes.surgeongeneral.gov/documents/2016\_SGR\_Full\_Report\_non-508.pdf, last seen on 16/01/2020.

<sup>&</sup>lt;sup>51</sup> Ibid.

<sup>&</sup>lt;sup>52</sup> J.M. Kinnunen, H. Ollila, El-Amin et al., Awareness and determinants of electronic cigarette use among Finnish adolescents in 2013: a population-based study, 24 Tobacco Control 264, (2015), available at https://tobaccocontrol.bmj.com/content/24/e4/e264, last seen on 16/02/2020.

ENDS. Despite the advertisement ban, every 10th adolescent reported having seen e-cigarette advertisements, mostly on Facebook.<sup>53</sup> Highlighting the rapid increase in ENDS experimentation among adolescents, Dr. Poonam Khetrapal Singh, the Regional Director of World Health Organisation, South-East Asia office, said that because there are "almost 8,000 different flavours, including fruit and candy-like flavours, there is legitimate concern that instead of reducing the number of smokers, e-cigarettes will actually serve as a gateway to nicotine addiction, and ultimately smoking, particularly for young people."<sup>54</sup>

### 3. ENDS use among Indian youth

A study in India with school students, teachers, parents and college students highlighted that ENDS were considered to be a non-tobacco, non-nicotine product.<sup>55</sup> The study also reported that there was confiscation of ENDS from all schools visited, while students reported high popularity, social acceptance, convenient availability and easy affordability of ENDS.<sup>56</sup>

### V. THE REGIME OF REGULATING ENDS GLOBALLY

There is no uniform system when it comes to regulating ENDS globally. Different countries have taken different approach towards regulating ENDS. They are being sold in pharmacies, supermarkets, kiosks, via the Internet, retail and specialized shops, markets/market stalls, on the street, bars and pubs and leisure venues such as casinos and bingo halls.<sup>57</sup> The

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<sup>&</sup>lt;sup>53</sup> Supra 250;

M.B. Steinberg, M.H. Zimmermann, C.D. Delnevoet al., *E-Cigarette Versus Nicotine Inhaler: Comparing the Perceptions and Experiences of Inhaled Nicotine Devices*, 29 Journal of General Internal Medicine 1444, (2014), available at https://www.ncbi.nlm.nih.gov/pubmed/24830741, last seen on 12/01/2020;

M. Hua, H. Yip&P. Talbot, Mining data on usage of electronic nicotine delivery systems (ENDS) from YouTube videos, 22 Tobacco Control 103, (2013), available at https://tobaccocontrol.bmj.com/content/22/2/103.info, last seen on 16/01/2020.

<sup>&</sup>lt;sup>54</sup> P.K. Singh, Only a smoke screen: Electronic cigarettes are not entirely harmless and need to be regulated, The Times of India (10/10/2014), available at https://timesofindia.indiatimes.com/blogs/toi-edit-page/only-a-smoke-screen-electronic-cigarettes-are-not-entirely-harmless-and-need-to-be-regulated/, last seen on 05/01/2020.

<sup>&</sup>lt;sup>55</sup> R. Shrivastav, P. Kathuria, M. Arora et al., (Mis)perceptions related to Electronic Nicotine Delivery Systems (ENDS) and hookah: making a case for policy strengthening through a multi-stakeholder qualitative study from New Delhi, India, 16 Tobacco Induced Diseases 469, (2018), available at https://doi.org/10.18332/tid/84580, last seen on 12/01/2020.

<sup>&</sup>lt;sup>57</sup> Electronic nicotine delivery systems Report by WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Russian Federation, October 13-18, FCTC/COP/6/10 (September, 2014), available at http://apps.who.int/gb/fctc/PDF/cop6/FCTC\_COP6\_10Rev1-en.pdf?ua=1, last seen on 17/01/2020.

worldwide sale and thereby regulation of ENDS has been very diverse given the diverse legal and constitutional mandates which national and municipal governments must adhere to. As per the report submitted to the Secretariat of the WHO FCTC, whether or not the Parties regulate ENDS, only a few countries are able to monitor sales levels of ENDS or their historical trends.<sup>58</sup>

In 2014, the sale of ENDS with nicotine was banned in 13 of the 59 countries that regulated them, including countries like, Brazil, the Seychelles, Singapore, Thailand and Uruguay that had laws banning the manufacturing, importation, distribution, and sale of ENDS.<sup>59</sup> Keeping with the Article 16 of the WHO FCTC, regardless of accompanying health claims and the presence or absence of tobacco or nicotine extracts in the ENDS, the Seychelles and Singapore consider ENDS as a tobacco imitation product and thus its manufacture, import, supply, distribution and sale is prohibited under their tobacco control laws. Brazil banned the sale, importation and advertisement of "any electronic device for smoking". In Canada, in the same way as manufacturers of nicotine gum and lozenges had to obtain pre-market approval, market authorization under the Food and Drugs Act, is required before importing, advertising, or selling ENDS products.<sup>60</sup> In the USA, ENDS and other products made or derived from tobacco can be regulated as "tobacco products" and are not drugs/devices unless they are marketed for therapeutic purposes.<sup>61</sup> However, in the UK, ENDS products could get marketing authorisation to be sold either as medicines or as consumer products. By 2017 the sale of ENDS was banned by 25 countries out of the 68 countries that regulated ENDS under their national laws.<sup>62</sup>

### VI. EARLY REGULATION OF ENDS IN INDIA

58 The Convention Secretariat calls Parties to remain vigilant towards novel and emerging nicotine and tohacco products WHO FCTC available at

tobacco products, WHO FCTC, available at https://www.who.int/fctc/mediacentre/news/2019/remain-vigilant-towards-novel-new-nicotine-tobacco-products/en/, last seen on 16/02/2020.

<sup>&</sup>lt;sup>59</sup> Electronic nicotine delivery systems Report by WHO, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Russian Federation, October 13-18, FCTC/COP/6/10 (September, 2014), available at http://apps.who.int/gb/fctc/PDF/cop6/FCTC\_COP6\_10Rev1-en.pdf?ua=1, last seen on 19/01/2020;

<sup>&</sup>lt;sup>60</sup> See *Country Laws Regulation E-cigarettes: A Policy Scan*, Global Tobacco Control, available at https://www.globaltobaccocontrol.org/e-cigarette/country-laws/view last accessed 22-02-2020.

<sup>&</sup>lt;sup>61</sup> Sottera, Inc. v. Food & Drug Administration, 627 F.3d 891.

<sup>&</sup>lt;sup>62</sup> R.D. Kennedy, A. Awopegba, E. De León, J.E. Cohen, *Global approaches to regulating electronic cigarettes*, 26 Tobacco Control 440, (2017), available at https://tobaccocontrol.bmj.com/content/tobaccocontrol/26/4/440.full.pdf, last seen on 18/01/2020.

ENDS were introduced to Indian markets about 10 years back in 2009-2010 and soon started gaining popularity, especially among school going youth. In absence of clear regulations ENDS were sold as recreational products, substitute products, cessation aids and general consumer products in the Indian markets both at the local vendor and through online shopping portals and internet sales. Though ENDS were not regulated in India, several directives on manufacture, sale, storage, distribution and use of nicotine were available. Most of the laws and regulations dealing with nicotine classify it as a poisonous substance and prohibit its use for human consumption. These include the Drugs and Cosmetics Act, 1940; Poisons Act, 1919; Insecticides Act, 1968; Environment Protection Act, 1986; Food Safety and Standards Act, 2006; and the Manufacture, Storage and Import of Hazardous Chemical Rules, 1989.

Considering that the safety and quality of ENDS has not been established, an expert panel on ENDS was constituted by MoHFW. 63 The expert panel recommended a complete ban on ENDS in 2014.64 It also suggested that until such time as their safety and effectiveness as cessation aids is clinically established and approved by the Drug Control Authority, sale of ENDS should be immediately prohibited under the Drugs and Cosmetics Act. The panel considered that ENDS could lead to addiction, particularly among the youth, and become a gateway to tobacco use in the country where already more than 5500 youth start tobacco use every day. 65 The Government of Punjab, in September 2013, had already issued an advisory declaring ENDS as an unapproved drug contravening the provisions of the Drugs and Cosmetics Act and directed all the drug inspectors to be vigilant about the spread of ENDS in the State.66

### 1. Hazardous and poisonous chemical

63 Ministry of Health and Family Welfare, Government of India, National Safety *Implementation* Framework.

(2018-2025),

https://main.mohfw.gov.in/sites/default/files/national%20patient%20safety%20impli mentation\_for%20web.pdf, last seen on 28/04/2020.

<sup>&</sup>lt;sup>64</sup> ET Bureau, India mulls total ban on e-cigarettes, as government panel says safety not established, Times (30/08/2014),Economic available https://economictimes.indiatimes.com/industry/cons-products/tobacco/india-mullstotal-ban-on-e-cigarettes-as-government-panel-says-safety-notestablished/articleshow/41223840.cms?from=mdr, last seen on 22/02/2020.

<sup>65</sup> Ibid.

<sup>66</sup> Nicotine preparations coming in form of E-Cigarettes is unapproved drug and contravenes the provisions of Drugs and Cosmetics Act, 1940, Food and Drugs Administration, Government of Punjab, Circular No. Drugs (7) Pb. 2013/16988-89, (05/09/2013), available at <a href="http://pbhealth.gov.in/ban\_e-CIgg.pdf&gt">http://pbhealth.gov.in/ban\_e-CIgg.pdf&gt</a>, last seen on 28/04/2020.

Nicotine is listed as a hazardous chemical under the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade (in force since 24 February 2004) and the Environment (Protection) Act, 1986 (in India);<sup>67</sup> and as a poison under the Poisons Act, 1919 (in India).<sup>68</sup> Therefore, manufacture, import, storage, distribution and sale of products containing nicotine in chemical form was highly restricted in India. Further, the Punjab and Haryana High Court imposed a ban on use of Nicotine in chemical form in 2012 while hearing a petition filed by Mr. Hemant Goswami of the Burning Brain Society, Chandigarh.<sup>69</sup>

In April 2014, a Punjab Sessions court sentenced a shopkeeper from Mohali city to three years in jail for selling ENDS in violation of the directions issued under the Drugs and Cosmetics Act, 1940.<sup>70</sup> The Court observed that, "E-cigarette contains nicotine in chemical form, which is highly addictive and potentially lethal. The youth take to such kind of addictive and potentially lethal products, and the offenders involved in promoting and selling such products should be dealt with sternly by law for the welfare of the society."<sup>71</sup> The Commissioner of Food and Drug Administration, Punjab also requested the MoHFW to prevent online sale of ENDS.<sup>72</sup>

### 2. Advisory from the MoHFW

With the expert panel recommendations and requests from states still pending consideration, civil society organizations finally approached the Delhi High Court for issuing directions to the Central Government to ban ENDS. On 21 August 2018, the High Court directed MoHFW to take regulatory measures to curb ENDS within a week.<sup>73</sup> Based on the Court's direction, on 28<sup>th</sup> August 2018, MoHFW issued an advisory to all states and union territories to ensure that "ENDS, e-cigarettes, heat-not-burn devices, vape, e-sheesha, e-nicotine flavoured hookah, and similar devices that enable nicotine delivery are not sold (including online sale), manufactured, distributed, traded, imported and advertised in their jurisdictions."<sup>74</sup> Several states complied with

 $^{73}$  Seema Sehgal v. Union of India and Others, W.P. (C) 10624/2017 & Criminal Appeal No. 33757/2018 (Delhi High Court, 07/09/2018).

<sup>&</sup>lt;sup>67</sup> Schedule 1, The Environment (Protection) Act, 1986.

<sup>&</sup>lt;sup>68</sup> The Punjab Poisons Possession and Sale Rules, 2014.

<sup>&</sup>lt;sup>69</sup> Burning Brain Society v. Union of India, (2013) 1 RCR (Cri) 736.

<sup>&</sup>lt;sup>70</sup> State of Punjab v. Parvesh Kumar, Sessions Case No. 03/19.05.2015.

<sup>&</sup>lt;sup>71</sup> N. Jain, *E-cigarette seller gets 3-year jail in Mohali*, The Tribune (15/04/2016), available at https://www.tribuneindia.com/news/archive/e-cigarette-seller-gets-3-year-jail-in-mohali-222736, last seen on 05/01/2020.

<sup>72</sup> Ibid.

<sup>&</sup>lt;sup>74</sup> Advisory on Electronic Nicotine Delivery Systems (ENDS) Including E-Cigarettes, Heat-Not-Burn Devices, Vape, E-Sheesha, E-Nicotine Flavoured Hookah, and the like Products, Ministry of Health and Family Welfare, Government of India Circular No. F.No-P-16012/19/2017-TC (28/08/2018), available at

this advisory and completely banned trade, commerce and use of ENDS.<sup>75</sup>

On 27 November 2018, the Central Board of Indirect Taxes and Customs (Anti-Smuggling Unit) directed all its officials to ensure implementation of this advisory and report all such consignments to the Assistant or Deputy Drugs Controller in their jurisdiction. <sup>76</sup> Based on the report of the Assistant or Deputy Drugs Controller, for any non-compliant consignments, action under the Drugs and Cosmetics Act, 1940 had to be initiated. <sup>77</sup>

Further, based on the advisory, on 22 February 2019, the Drug Controller General of India issued a directive to all state and union territory drug controllers that since no e-cigarettes or like nicotine delivery devices are approved by the authority, sale, manufacture, distribution, trade, import and advertisement of e-cigarettes and the like products is banned. The directive imposed the ban on both retail and online sales of ENDS.<sup>78</sup>

Further, the Ministry of Electronics and Information Technology (MEITY) proposed an amendment to the Information Technology (Intermediary Guidelines) Rules 2018 to ban the advertisement of anything that threatens public health or safety. It specifically mentioned that intermediaries should inform users to prevent transmission of information on tobacco, alcohol and ENDS.<sup>79</sup>

In addition, Section 2 of the Poisons Act, 1919 read with section 8 provides power to the state governments to frame rules to carry out the

https://www.tobaccocontrollaws.org/files/live/India/India%20%20MOHFW%20Advisory%20on%20ENDS.pdf, last seen on 05/01/2020.

<sup>&</sup>lt;sup>75</sup> Yadav & S. Glantz, India: government ordinance to ban ENDS with immediate effect,

<sup>28</sup> Tobacco Control 599, 602 (2019), available at https://tobaccocontrol.bmj.com/content/28/6/599, last seen on 18/01/2020.

<sup>&</sup>lt;sup>76</sup>Yadav, *Smoking e-cigarettes is more injurious to health*, The Hindu (23/07/2019), available at https://www.thehindu.com/opinion/op-ed/smoking-e-cigarettes-is-more-injurious-to-health/article28658584.ece, last seen on 28/04/2020.

<sup>&</sup>lt;sup>77</sup>Advisory on Electronic Nicotine Delivery Systems (ENDS) including eCigarettes, Heat-Not-Burn devices, Vape, e-Sheesha, e-Nicotine Flavoured Hookah, and the like products-reg, Ministry of Finance, Government of India Circular No. 46/2018-Custom (27/11/2018), available at

https://www.tobaccocontrollaws.org/files/live/India/India%20-

<sup>%20</sup>MoF%20Circular%20on%20ENDS.pdf, last seen on 28/04/2020.

<sup>&</sup>lt;sup>78</sup> ENDS and the like devices that enable nicotine delivery system reg, Ministry of Health and Family Welfare, Government of India Circular No. Import/Misc./14/2019-DC (22/02/2019), available at

https://www.tobaccocontrollaws.org/files/live/India/India%20-

<sup>%20</sup>DCGI%20Letter%20on%20ENDS.pdf, last seen on 28/04/2020.

<sup>&</sup>lt;sup>79</sup> Anoo Bhuyan, *Three Ministries Advance Regulations to Control E-Cigarettes*, The Wire (8/01/2019), available at https://thewire.in/health/three-ministries-advance-regulations-to-control-e-cigarettes, last seen on 05/01/2020.

purposes and objects of the Act. The states which have listed nicotine as poison under the rules can regulate or restrict the use of nicotine and therefore of ENDS as well. For instance, the State of Punjab, Haryana and Karnataka banned the manufacture, sale and distribution of ENDS as it is in contravention with the Poison Rules read with the Poisons Act within these states.<sup>80</sup>

#### 3. Ordinance to ban ENDS in India

The advisory by the MoHFW was challenged in the Delhi High Court by Piush Ahluwalia, an ENDS user. He contended that the advisory violated his fundamental rights under Article 14, 19 and 21 of the Constitution of India in as much as it deprived him from using less harmful products compared to cigarettes. Hearing the petition, the Court held that it did not consider that any interference with the said advisory was warranted as the MoHFW's advisory was not binding in nature and the states were free to take an informed view on its implementation. The ENDS ban decision of the state of Jammu Kashmir, Karnataka and Tamil Nadu were also challenged in the High Courts of these respective states.

The MoHFW had initially planned to implement the ban on ENDS under the Drugs and Cosmetics Act, 1940 as an unapproved drug and device. However, as a result of the litigation against its advisory and the several state orders under different laws, it finally decided to take the emergency law making route to implement the ban on ENDS by issuing an ordinance to prevent ENDS from becoming an "epidemic" among children and young adults.<sup>86</sup>

<sup>80</sup> Indian Council of Medical Research, White Paper on Electronic Nicotine Delivery System, 149(5) Indian Journal of Medical Research 574, (2019), available at http://www.ijmr.org.in/article.asp?issn=0971-

<sup>5916;</sup>year=2019;volume=149;issue=5;spage=574;epage=583;aulast=Indian, last seen on 22/02/2020.

<sup>81</sup> Piush Ahluwalia v. Union of India, W.P.(C) 12163/2018 (Delhi High Court, 2018).

<sup>&</sup>lt;sup>82</sup> AVI has legally challenged vape bans, Vape India, available at http://vapeindia.org/india/legal/, last seen on 28/04/2020.

 $<sup>^{83}</sup>$  Council for Harm Reduced Alternatives v. State of Karnataka and Others, W.P. No. 36696/2017 (Karnataka High Court, 22/08/2017).

<sup>84</sup> Electronic Cigarettes: Regulatory Framework In India, Ikigai Law, available at https://www.ikigailaw.com/electronic-cigarettes-regulatory-framework-in-india/#acceptLicense, last seen on 05/01/2020.

85 Ibid.

<sup>&</sup>lt;sup>86</sup> The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Ordinance, 2019;

Also see A. Kalra, *India proposes ban on e-cigarettes, with jail terms for offenders - government documents*, Reuters (22/08/2019), available at https://www.reuters.com/article/us-india-ecigarettes-exclusive/exclusive-india-proposes-ban-on-e-cigarettes-with-jail-terms-for-offenders-government-documents-idUSKCN1VC1RI, last seen on 05/01/2020.

The tobacco and vaping industries raised alarm that such a law will result in severe loss of revenue to those engaged in the business and especially the tobacco farmers.<sup>87</sup> On the other hand the civil society and health professionals refuted the industry claims and demanded an early implementation of the ban.<sup>88</sup> As a result, a Group of Ministers ("GoM"), led by Finance Minister, Ms. Nirmala Sitharaman, was constituted in September 2019 to review the MoHFW's proposed law.<sup>89</sup> The trade representatives of ENDS and vapers association approached the GoM seeking fair trial. 90 The proposal was approved by the group of ministers and accepted by the cabinet on 18 September 2019 and on the same day 'the Prohibition of Electronic Cigarettes (Production, Manufacture, Export, Transport, Sale, Distribution, Storage Import, Advertisement) Ordinance, 2019' was promulgated. Enforcement of the ordinance began in India with state governments issuing public notices to both inform the public and to ensure compliance with the law.<sup>91</sup>

While the government was preparing to get the ordinance passed into a legislation by the parliament, JUUL, a multinational ENDS giant, funded local ENDS importers to challenge the ordinance before the courts. <sup>92</sup> Two e-cigarette importers, Plume Vapour and Woke Vapours, challenged the Ordinance before the Calcutta High Court, Kolkata. <sup>93</sup> However, MoHFW remained committed to implementation of the ban in its present form and informed the Court of its intent to prevent the present and future generations from nicotine addiction. With the endorsement of

<sup>87</sup> A. Yadav & S. Glantz, India: government ordinance to ban ENDS with immediate effect,

<sup>28</sup> Tobacco Control 599, 602 (2019), available athttps://tobaccocontrol.bmj.com/content/28/6/599, last seen on 18/01/2020.

<sup>&</sup>lt;sup>88</sup> A. Yadav, *Smoking e-cigarettes is more injurious to health*, The Hindu 23/01/2019), available at https://www.thehindu.com/opinion/op-ed/smoking-e-cigarettes-is-more-injurious-to-health/article28658584.ece, seen on 05/01/2020.

<sup>&</sup>lt;sup>89</sup> PTI, *Draft ordinance to ban e-cigarettes with jail terms for violators to be examined by GoM*, Economic Times (28/08/2019), available at https://health.economictimes.indiatimes.com/news/industry/draft-ordinance-to-ban-e-cigarettes-with-jail-terms-for-violators-to-be-examined-by-gom/70864157, last seen on 22/02/2020.

<sup>&</sup>lt;sup>90</sup> Trade representatives seek GoM hearing over bringing ordinance to ban ENDS, Outlook India (3/09/2019), available at https://www.outlookindia.com/newsscroll/trade-representatives-seek-gom-hearing-over-bringing-ordinance-to-ban-ends/1611039, last seen on 22/02/2020.

<sup>&</sup>lt;sup>91</sup> Cabinet approves Promulgation of the Prohibition of Electronic Cigarettes Ordinance, Press Information Bureau, Government of India, available at https://pib.gov.in/PressReleseDetail.aspx?PRID=1585437, last seen on 22/02/2020.

<sup>&</sup>lt;sup>92</sup> M. Davies, J. Kasperkevic & M. Chapman, *JUUL spreads over the world as home market collapses in scandal*, The Bureau of Investigative Journalism (21/11/19), available athttps://www.thebureauinvestigates.com/stories/2019-11-21/juul-spreads-over-theworld-as-home-market-collapses-in-scandal, last seen on 20/01/2020.

<sup>93</sup> Plume Vapour Private Ltd. & Anr. v. Union of India, 2019 SCC OnLine Cal 7084

the Ordinance by the Parliament, the Court dismissed the two petitions.<sup>94</sup> While world governments have struggled in regulating and preventing the ENDS epidemic, the Prime Minister of India highlighted his Government's decisive action against ENDS to deal with the worrisome craze of ENDS among youth during his speech at the UN on September 23, 2019.<sup>95</sup>

### 4. The present legal position

The Prohibition of Electronic Cigarettes Act, 2019<sup>96</sup> (the Act) completely prohibits the Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement of ENDS to prevent their negative health impacts on the public, especially youth. The key features of the law include:

Law applicable all over India: In the public interest the Parliament decided to take control of the ENDS industry into its control under section 2 of the Act, and therefore made the law applicable across India. Considering the varying regulations for ENDS ban by various states, this law envisioned and implemented a uniform national policy on ENDS ban.<sup>97</sup>

Definition of ENDS: The Act defines electronic cigarettes to mean "an electronic device that heats a substance, with or without nicotine and flavours, to create an aerosol for inhalation and includes all forms of Electronic Nicotine Delivery Systems, Heat Not Burn Products, e-Hookah and the like devices, by whatever name called and whatever shape, size or form it may have, but does not include any product licensed under the Drugs and Cosmetics Act, 1940; Explanation.—For the purposes of this clause, the expression "substance" includes any natural or artificial substance or other matter, whether it is in a solid state or in liquid form or in the form of gas or vapour;" "98

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<sup>94</sup> Ibid.

<sup>&</sup>lt;sup>95</sup> PM's remarks at the UNGA high-level meeting on universal health coverage, PM India, available at https://www.pmindia.gov.in/en/news\_updates/pms-remarks-at-the-unga-high-level-meeting-on-universal-health-coverage/, last seen on 22/02/2020.

<sup>&</sup>lt;sup>96</sup> The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

<sup>&</sup>lt;sup>97</sup> M. Davies, J. Kasperkevic & M. Chapman, *JUUL spreads over the world as home market collapses in scandal*, The Bureau of Investigative Journalism (21/11/19), available athttps://www.thebureauinvestigates.com/stories/2019-11-21/juul-spreads-over-theworld-as-home-market-collapses-in-scandal, last seen on 20/01/2020.

<sup>&</sup>lt;sup>98</sup> S. 3 (d), The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

Therefore, the law not only closes the Indian market for all kinds of electronic cigarettes from different generations, but also prohibits heat not burn devises, e-hookah and any other similar devises that could be introduced in the market in future e.g ultrasonic nicotine delivery devices.<sup>99</sup>

**Ban on ENDS:** The ban on ENDS under the law is a comprehensive one and extends to production, manufacturing, import, export, transport, sale and distribution whether directly or indirectly, as a complete or in any part thereof. The law also requires that no person shall directly or indirectly advertise or take part in any advertisement that directly or indirectly promotes use of ENDS. The law also requires that no person shall directly or indirectly promotes use of ENDS.

Ban on storage of ENDS: The Act also prohibits storage of any stock of ENDS and requires that all existing stocks are declared and submitted to the nearest office of the authorised officer. Such authorised officer shall take necessary measures for the disposal of the stocks as per the existing law in force to that regard. Such authorised officer is also vested with the power to enter, search and seize without warrant if he has reason to believe that provisions of the Act have been or are being violated.

**Penalties:** Violation of section 4 of the law attracts up to one-year imprisonment or a fine of up to Rupee one lakh or both for first offence and up to three years imprisonment and a fine up to Rupee five lakh for a subsequent offence. Whoever is guilty of storing ENDS will be liable to imprisonment of up to six months or a fine of Rupees fifty thousand or both. Offences under Section 4 are cognizable 107 and the Court of Judicial Magistrate of

<sup>&</sup>lt;sup>99</sup> This next generation devises work on ultrasonic high frequency vibrations to generate aerosol instead of a heating coil or other heating elements.

<sup>&</sup>lt;sup>100</sup> S. 4 (i), The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

<sup>&</sup>lt;sup>101</sup> S. 4(ii), The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

<sup>&</sup>lt;sup>102</sup> S. 5(a), The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

<sup>103</sup> S. 5 (b), The Prohibition of Electronic Cigarettes (Production, Manufacture, Import,

Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

104 S. 6, The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

<sup>&</sup>lt;sup>105</sup> S. 7, The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

<sup>&</sup>lt;sup>106</sup> S. 8, The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

<sup>&</sup>lt;sup>107</sup> S. 13, The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

the First Class has been designated for the trial of all offences under the Act.<sup>108</sup> However, a court shall only take cognizance of the violation of the provisions of this Act on the complaint of an authorised officer (i.e., any police officer not below the rank of a sub-inspector or other person so designated by the central or state government).<sup>109</sup>

**Ban on use of ENDS:** Although the Act does not directly ban the use of ENDS, the lawmakers clearly intended that no one should use them in the country by prohibiting storage of these devices. This was also expressed by the Health Ministry before the Calcutta High Court.<sup>110</sup>

**Direction for compliance:** To ensure effective implementation of the provisions of the law across the country, the Union Health Ministry issued directives to all the concerned officials in the states and union territories to take necessary measures to implement the law. State authorities were asked to undertake a month-long drive with participation of police and other concerned departments. The Union health ministry also sought an action-taken report from all states and union territories with details of the case registered, stock seized, and number of traders who have deposited list of ENDS in nearest police station. Several states have further directed their state and local agencies to ensure compliance with the law.

### VII. GLOBAL BEST PRACTICE

By implementing a comprehensive ban on ENDS, India has not only complied with the recommendations of the Sixth Session of the Conference of Parties of WHO FCTC that invited all Parties to consider

<sup>&</sup>lt;sup>108</sup> S. 9, The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

<sup>&</sup>lt;sup>109</sup> S. 12, The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

<sup>&</sup>lt;sup>110</sup> Plume Vapour Private Ltd. &Ors. v. Union of India &Ors., 2019 SCC OnLine Cal 7084;

Also see A. Kalra, *India says e-cigarette ban implies use of devices also prohibited*, Reuters(18/11/2019), available athttps://www.reuters.com/article/us-india-ecigarettes/india-says-e-cigarette-ban-implies-use-of-devices-also-prohibited-idUSKBN1XS1DR, last seen on 17/01/2020.

<sup>111</sup> Proper Implementation of the provisions laid down in the Prohibition of Electronic Cigarettes, (production, manufacture, import, transport, sale, distribution, storage and advertisement) ordinance, 2019, Ministry of Health and Family Welfare, Government of India Notification No. D.O.No.P.16012/23/2019-TC (23/12/2019), available athttp://www.odishapolicecidcb.gov.in/sites/default/files/Ordinance.pdf, last seen on 28/04/2020.

prohibiting or regulating the use of e-cigarettes in their countries<sup>113</sup>, but has also followed the global best practice already implemented in over 30 countries that have banned manufacture, trade and advertisement of ENDS while countries like Singapore and Cambodia have also banned its possession.<sup>114</sup> It has also presented an example to emulate for other countries that are still in the process of regulating or imposing a ban on ENDS within in their jurisdiction including the USA which is trying to curb the menace of ENDS epidemic among youth.<sup>115</sup>

#### VIII. LEGAL IMPLICATIONS

The Constitution of India obligates the Government to take measures to improve public health and in doing so the Government shall endeavour to bring about prohibition of the consumption except for medicinal purposes of 'intoxicating drinks and of drugs which are injurious to health'. The present Act imposing comprehensive prohibition on ENDS envisions to meet this obligation. The law is also in line with the existing provisions under the Juvenile Justice (Care and Protection of Children) Act, 2015 which prohibits access to any intoxicating liquor, any narcotic drug, tobacco product, or psychotropic substance to a person below the age of 18 years. It is well known that nicotine is a unique psychotropic substance that both stimulates and depresses functions of and affects the central nervous system. However, it must be noted that the ban on ENDS is imposed on over the counter sale of ENDS as a recreational or harm reduction or alternative to tobacco consumer

<sup>&</sup>lt;sup>113</sup> Report of the sixth session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control, Conference of the Parties to the WHO Framework Convention on Tobacco Control, Russian Federation, October 13-18, 2014, available at https://www.who.int/fctc/cop/sessions/COP6\_report\_FINAL\_04122014.pdf?ua=1, last seen on 17/01/2020.

<sup>&</sup>lt;sup>114</sup> Advisory on Electronic Nicotine Delivery Systems (ENDS) Including E-Cigarettes, Heat-Not-Burn Devices, Vape, E-Sheesha, E-Nicotine Flavoured Hookah, and the like Products, Ministry of Health and Family Welfare, Government of India Circular No. F.No-P-16012/19/2017-TC (28/08/2018), available at

https://www.tobaccocontrollaws.org/files/live/India/India%20-

<sup>%20</sup>MOHFW%20Advisory%20on%20ENDS.pdf, last seen on 05/01/2020.

<sup>&</sup>lt;sup>115</sup> The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Bill, 2019, PRS Legislative Brief, available athttp://prsindia.org/node/843494/chapters-at-a-glance, last seen on 17/01/2020;

B. Lovelace, *The FDA bans most fruit- and mint-flavored nicotine vaping products to curb teen use*, CNBC (2/1/2020), available athttps://www.cnbc.com/2020/01/02/fda-issues-ban-on-some-flavored-vaping-products.html, last seen on 17/01/2020.

<sup>&</sup>lt;sup>116</sup> Art. 47, the Constitution of India.

<sup>&</sup>lt;sup>117</sup> S. 77, Juvenile Justice (Care and Protection of Children) Act, 2015.

<sup>&</sup>lt;sup>118</sup> E.F. Domino, Nicotine: A Unique Psychoactive Drug —Arousal With Skeletal Muscle Relaxation, 22 Psychopharmacology Bulletin 870, (1986);

Effects of Nicotine on Biological Systems, 502 (Adlkofer & Thurau, 1991);

J.B. Murray, *Nicotine as a psychoactive drug*, 125 The Journal of Psychology 5, (1991), available athttps://www.ncbi.nlm.nih.gov/pubmed/2033559, last seen on 19/01/2020.

product. Law exempts from its ambit any such product that is licensed under the Drugs and Cosmetics Act, 1940.<sup>119</sup> This exemption provides room for manufacturers willing to sell their products as a regulated drug or device with due license from the Central Drugs Standard Control Organization of India.

The law also paves way for the Government of India to revive the amendment of COTPA for the same reasons as ENDS ban legislation. Government should progressively target to make the country tobaccofree by 2030 which will prevent more than 13.5 lakh annual deaths that happen due to tobacco use and annual economic loss of rupees 1,04,500 crore due to tobacco induced diseases. Given that tobacco use is one of the most significant risk factors for Tuberculosis, such a targeted tobacco control effort will also accelerate progress towards meeting the objectives of the National Tuberculosis Elimination Programme of ending Tuberculosis by 2025.

In January this year, a challenge to the ENDS ban legislation was returned by the Supreme Court suggesting that the petitioner approach the Delhi High Court in the matter. <sup>125</sup> The Delhi High Court was already apprised of pre-legislation petitions both against <sup>126</sup> and in support <sup>127</sup> of the ban on ENDS. As no court has given any adverse directive against the law, its implementation continues in the country. However, given the

22/02/2020.

Appeal No. 33757/2018 (Delhi High Court, 07/09/2018).

<sup>&</sup>lt;sup>119</sup> S. 3(d), The Drugs and Cosmetics Act, 1940.

<sup>&</sup>lt;sup>120</sup> Ministry of Health and Family Welfare, Government of India, *Withdrawal of amendment to Cigarettes and Other Tobacco Products Act, 2003*, available at https://mohfw.gov.in/sites/default/files/NOTICE(1).pdf, last seen on 19/01/2020.

<sup>&</sup>lt;sup>121</sup> Ministry of Health and Family Welfare, Government of India, *Global Adult Tobacco Survey 2, India 2016-17*, available at

https://www.who.int/tobacco/surveillance/survey/gats/GATS\_India\_2016-

<sup>17</sup> FactSheet.pdf, last seen on 19/01/2020.

<sup>&</sup>lt;sup>122</sup> Ministry of Health and Family Welfare, Government of India, Report on Economic Burden of Tobacco Related Diseases in India, available at

https://ntcp.nhp.gov.in/assets/document/surveys-reports-publications/Economic-Burden-of-Tobacco-Related-Diseases-in-India-Report.pdf, last seen on 19/01/2020.

<sup>123</sup> P. Jha, B. Jacob, V. Gajalakshmi, et al., *A nationally representative case–control study of smoking and death in India*, 358 The New England Journal of Medicine 1137, (2008), available athttps://www.nejm.org/doi/full/10.1056/NEJMsa0707719, last seen on

<sup>&</sup>lt;sup>124</sup> M. Pai, S. Bhaumik& S.S. Bhuyan, *India's plan to eliminate tuberculosis by 2025: converting rhetoric into reality*, 2 BMJ Global Health 1, (2017), available athttps://gh.bmj.com/content/2/2/e000326, last seen on 22/02/2020.

<sup>&</sup>lt;sup>125</sup> SC declines to hear plea challenging Bill banning E-Cigarettes, Indian Legal (13/01/2020), available athttps://www.indialegallive.com/constitutional-law-news/supreme-courtnews/sc-declines-hear-plea-challenging-bill-banning-e-cigarettes-82668, last seen on 19/01/2020.

Piush Ahluwalia v. Union of India, W.P.(C) 12163/2018 (Delhi High Court, 2018)
 Seema Sehgal v. Union of India and Others, W.P. (C) 10624/2017 & Criminal

pending litigations the matter is far from final as we wait for the law to clear these judicial tests in due course of time.

### IX. PUBLIC HEALTH IMPLICATIONS

While the government is struggling to contain substance abuse in the country, especially among youth and young adults, nicotine addiction in the form of ENDS use could present yet another challenge for the already burdened health systems. According to experts, "India is already struggling to control several addictions such as tobacco, alcohol, areca nut and cannabis. Adding a new addiction would only worsen the situation." Globally, manufacturers of ENDS have not claimed any therapeutic value of ENDS including its use for promoting tobacco or smoking cessation. Evidence suggest that more tobacco users using ENDS end up being dual users and never able to quit the nicotine addiction. 129 On the contrary, it entices minors to take up smoking. Considering that nicotine is a psychoactive drug and is also a carcinogen, the timely action by the Government to ban ENDS will go a long way in preventing ENDS access among minors and other vulnerable populations while preventing an emerging public health threat from taking an epidemic proportion in the country.

Moreover, ENDS use is not an isolated phenomenon but affects use of combustible cigarettes, the known risks of which are extremely high. Given the dual use and gateway impact of ENDS use, especially among youth and young adults, the public health effect of ENDS is severely adverse with the inherent risks of ENDS coupled with an increased risk of conventional smoking. In absence of credible evidence of ENDS being effective in smoking cessation and its impending threat of becoming a youth epidemic, the net public health impact of the present law shall be distinctly positive.

### X. CONCLUSIONS

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<sup>&</sup>lt;sup>128</sup> P. Chaturvedi& P.C. Gupta, Four fake narratives the tobacco lobby is floating to undermine India's e-cigarette ban, Scroll.in (30/09/2019), available athttps://scroll.in/article/938799/four-fake-narratives-the-tobacco-lobby-is-floating-to-undermine-indias-e-cigarette-ban, last seen on 19/01/2020.

<sup>129</sup> S.A. Glantz & D.W. Bareham, *E-Cigarettes: Use, Effects on Smoking, Risks, and Policy Implications*, 39 Annu Rev Public Health 215 (2018), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6251310/, last seen on 22/02/2020.

130 D.N. Bhatta & Stanton A. Glantz, *Association of E-Cigarette Use With Respiratory Disease Among Adults: A Longitudinal Analysis*, 58 American Journal of Preventive Medicine 182, (2020), available at https://www.ajpmonline.org/article/S0749-3797(19)30391-5/fulltext, last seen on 22/02/2020.

In the last decade, various kinds of ENDS have been promoted as alternative to conventional cigarettes but none of them have been able to convincingly establish itself for smoking cessation. Globally, ENDS have raised more questions than answers to conventional smoking. The disease and deaths in several cities of the USA due to EVALI since July 2019 has been the lowest point for ENDS since its use began gaining popularity in the late 2000s and wide proliferation in the 2010s. Before it could take roots in India, the Government of India treaded a cautious path by prohibiting unrestricted production, manufacture, import, export, transport, sale, distribution, storage and advertisement of ENDS as a consumer product. In as much as nicotine is an addictive, psychotropic carcinogen, the pre-emptive action by MoHFW is in public interest and upholds the constitutional right to health of every Indian citizen.