

IN THE HIGH COURT OF KARNATAKA AT BENGALURU
ORIGINAL JURISDICTION
W.P. NO.36696/2017 (PIL)

BETWEEN:

COUNCIL FOR HARM REDUCED ALTERNATIVES

...PETITIONER

AND

STATE OF KARNATAKA

...RESPONDENT

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		<p>found to cause lung cancer, chronic obstructive pulmonary disease and vascular disease.</p> <p>Extensive studies into the chemical composition of e-liquids in Electronic Nicotine Delivery Systems have shown that it contains a substantially lower number of chemicals in comparison to the thousands present in cigarettes.</p> <p>Studies were conducted by Public Health England, shows that the main chemical ingredients used in Electronic Nicotine Delivery Systems are found in the e-liquid solution which is heated to generate vapor and this e-liquid has been identified as water, nicotine, propylene glycol, vegetable glycerine and typically also some flavouring.</p> <p>Further, a study conducted by Dr. Marina Murphy, Head of Scientific Media Relations, Research & Development at British American Tobacco, to compare the effects of smoke from tobacco cigarettes and vapor from ENDS based on stress, damage and disease caused to cells shows that tobacco cigarette smoke activates the stress response of the cells, causes double strand breaks in DNA and promotes formation of tumor. In comparison, ENDS showed no visible effects on the cells.</p> <p>There are numerous studies, research and analysis that suggest that Electronic Nicotine Delivery Systems in comparison to tobacco cigarettes and other tobacco products are less harmful and contain far lesser toxins and thereby cause reduced level of harm. Furthermore, there are also studies, research and analysis which suggest that Electronic Nicotine Delivery Systems are an effective means of curbing addiction to tobacco cigarettes and can be successfully used in smoking de-addiction programmes.</p> <p>Electronic Nicotine Delivery Systems do not contain tobacco, which essentially means that an Electronic Nicotine Delivery Systems user would still get their required dose of nicotine without having to ingest the 4800 chemicals contained in cigarette smoke. Moreover, E-liquids which are used in Electronic Nicotine Delivery Systems are available in various nicotine strengths, from zero to higher levels. This helps an Electronic Nicotine Delivery Systems user to control their nicotine intake.</p> <p>Electronic Nicotine Delivery Systems devices, when tested to identify their effects on passive smokers, turned out to be eight times lower than the harm posed by tobacco cigarettes to passive smokers.</p>
2.	15.06.2016	<p>The Respondent on 15 June 2016 issued the Circular HFW/126/CGE/2016 banning the sale (including online sale), manufacture, distribution, trade, import and advertisement of Electronic Nicotine Delivery Systems, its parts and components in any shape or size of cartridges containing nicotine in the interest of public.</p> <p>The Circular passed by the Respondent does not state under which provision or under which statute of law it has been issued. The Drugs and Cosmetics Act 1940 under section 18 provides a right to the State Government to issue a notification in the official gazette prohibiting manufacture and sale of certain drugs and cosmetics, which would be read as part of the Drugs and Cosmetics Act 1940 itself. However, in the present case the Respondent has merely issued a circular which is not notified in the official gazette.</p>
3.	19.06.2016	<p>An application was filed before the Tobacco Control Division of the Union Health Ministry under the Right to Information Act 2005, wherein specific information with</p>

		regards to studies or research conducted by any state department body that says electronic cigarettes cannot be used for smoking cessation and further sought for information with regards to any study or research conducted by the Public Health Department on electronic cigarette technology.
3.	21.07.2016	The reply received from the Tobacco Control Division of the Union Health Ministry to an application filed under the Right to Information Act 2005 states that the Respondent for the purpose of arriving at a decision to ban ENDS revealed that no study, research or analysis is available with them or relied upon by them prior to issuing the Circular.

Being aggrieved by the Circular HFW/126/CGE/2016 banning the sale (including online sale), manufacture, distribution, trade, import and advertisement of Electronic Nicotine Delivery Systems, the Petitioner is before this Hon'ble Court. It is submitted that there are numerous studies, research and analysis that suggest that Electronic Nicotine Delivery Systems in comparison to tobacco cigarettes and other tobacco products are less harmful and contain far lesser toxins and thereby cause reduced level of harm. Furthermore, there are also studies, research and analysis which suggest that Electronic Nicotine Delivery Systems are an effective means of curbing addiction to tobacco cigarettes and can be successfully used in smoking de-addiction programmes. However, the Circular does not provide any reasoning behind banning ENDS when there are other items such as tobacco cigarettes which contain nicotine but have not been banned nor does it provide any scientific evidence as to why ENDS are more harmful than other nicotine containing items such as tobacco cigarettes, and deserve to be banned when tobacco cigarettes are not banned. Having no other alternative or efficacious remedy in the matter, the Petitioner is constrained to approach this Hon'ble Court for relief, by way of preferring this Writ Petition. Hence this Writ Petition.

Place : Bangalore

Date: 22nd August 2017

COUNSEL FOR THE PETITIONER

IN THE HIGH COURT OF KARNATAKA AT BENGALURU
ORIGINAL JURISDICTION
W.P. NO. 36696/2017 (PIL)

BETWEEN:

COUNCIL FOR HARM REDUCED ALTERNATIVES

Having its registered office at

63, Floor 2, A & B Municipal IND EST
Dainik Shivneri Marg, Worli, Mumbai
Mumbai City, Maharashtra, India – 400018
Represented by its member,
Mr. Hoshang Major

...PETITIONER

AND

STATE OF KARNATAKA,
Represented by its Chief Secretary
Vidhana Soudha
Ambedkar Veedhi
Bengaluru 560 001

...RESPONDENT

MEMORANDUM OF WRIT PETITION UNDER ARTICLE 226 & 227 OF THE CONSTITUTION OF INDIA

The Petitioners above named most respectfully submit as follows-

I. **ADDRESS OF SERVICE :**

The addresses of the parties are as stated in the cause title above. The Petitioner may also be served through their counsel Pingal Khan, Prashanth B.K and Harish Sasikumar, **Ashlar Law**, having their office at **411 'B', 4th Floor, Mittal Towers, M.G Road, Bangalore - 01**.

- II. The Petitioner is filing this Writ Petition under Article 226 of the Constitution seeking the issuance of a writ of certiorari quashing the Circular HFW/126/CGE/2016 dated 15 June 2016 issued by the Respondent ("Circular"). The Petitioner is also seeking issuance of a writ of mandamus directing the Respondent to permit the use sale and manufacturing and of Electronic Nicotine Delivery Systems ("ENDS"). A copy of the impugned circular is produced as **Annexure A**.

FACTUAL BACKGROUND

1. The Petitioner is a Section 8 company, registered under the provisions of The Companies Act, 2013. The Petitioner as its name suggests is an organization that works towards harm reduction in relation to the use of tobacco and also supports all other alternatives to reduce the harm caused by the use of cigarettes. Despite increasing public awareness about the ill-effects of cigarette smoking and millions of deaths and diseases attributable to cigarette smoking, many cigarette smokers are unwilling- or unable- to cease nicotine and tobacco abstinence. Conventional smoking cessation programmes generally present smokers with two unpleasant alternatives - quit or die. A third alternative, tobacco harm reduction, involves the use of alternative sources of nicotine including smokeless tobacco products. The use of such products is an effective substitute for tobacco cigarettes, and is part of an overall de-addiction programme. The Petitioner is an advocate of such alternatives to the use of conventional cigarettes which enables cigarette smokers to switch to safer methods of nicotine consumption with the overall objective of achieving de-addiction. The Petitioner aims to spread awareness amongst smokers with regards to alternatives to the use of conventional cigarettes whereby educating and empowering the consumers to make informed choices. The Petitioner is represented by its member Mr. Hoshang Major. A copy of the Board Resolution authorizing Mr. Hoshang Major to file this petition on behalf of Council for Harm Reduced Alternatives is produced at **Annexure B**.
2. The Respondent is the State of Karnataka represented by its Chief Secretary. The Respondent is "State" within the meaning of Article 12 of the Constitution of India.

3. The Respondent on 15 June 2016 issued the Circular banning the sale (including online sale), manufacture, distribution, trade, import and advertisement of ENDS, its parts and components in any shape or size of cartridges containing nicotine in the interest of public. The Circular states that ENDS contain chemical/drugs like nicotine with propylene glycol as main ingredients have adverse effect to the public health. It further states that nicotine is a chemical substance and it is addictive in nature and poisonous to human health. Further, the Circular states that nicotine in food products is banned under the Food Safety and Standard Act 2006 and the relevant rules and notifications thereunder and nicotine is only allowed as an aid for de-addiction in nicotine replacement therapy under the Drugs and Cosmetics Act 1940, and is not allowed for any other purpose under law. In addition, the Circular states that nicotine gums/lozenges of strength 2mg and 4 mg and nicotine transdermal therapeutic patches are the only nicotine containing drugs approved by the Drugs Controller General (India) as an aid for de-addiction in nicotine replacement therapy. Lastly, the Circular states that ENDS are being sold, illegally (including online sale), without obtaining valid license from appropriate authority specified by law. Therefore, from the reading of the Circular, it appears that the Respondent has banned the use and sale of ENDS due to it containing nicotine.

4. The Circular passed by the Respondent does not state under which provision or under which statute of law it has been issued. The Drugs and Cosmetics Act 1940 under section 18 provides a right to the State Government to issue a notification in the official gazette prohibiting manufacture and sale of certain drugs and cosmetics, which would be read as part of the Drugs and Cosmetics Act 1940 itself. However, in the present case the Respondent has merely issued a circular which is not notified in the official gazette. Based on this it would be trite to state that this Circular is merely an administrative order passed by the Respondent which does not have the authority of law.

5. Further, the Circular does not provide any reasoning behind banning ENDS when there are other items such as tobacco cigarettes which contain nicotine but have not been banned. This approach is plainly discriminatory. The Circular also does not provide any scientific evidence as to why ENDS are more harmful than other nicotine containing items such as tobacco cigarettes, and deserve to be banned when tobacco cigarettes are not banned. On 19.06.2016 an application was filed before the Tobacco Control Division of the Union Health Ministry under the Right to Information Act 2005 ("**RTI Application**"), wherein specific information with regards to studies or research conducted by any state department body that says electronic cigarettes cannot be used for smoking cessation and further sought for information with regards to any study or research conducted by the Public Health Department on electronic cigarette technology, however, the reply received from the Tobacco Control Division of the Union Health Ministry to the RTI Application seeking the scientific data such as studies/research/analysis which were conducted by the Respondent for the purpose of arriving at a decision to ban ENDS revealed that no study, research or analysis is available with them or relied upon by them prior to issuing the Circular. A copy of the reply to the RTI Application filed is produced as **Annexure C**.

6. At this juncture, it is relevant to mention that there are numerous studies, research and analysis that suggest that ENDS in comparison to tobacco cigarettes and other tobacco products are less harmful and contain far lesser toxins and thereby cause reduced level of harm. Furthermore, there are also studies, research and analysis which suggest that ENDS are an effective means of curbing addiction to tobacco cigarettes and can be successfully used in smoking de-addiction programmes.

ENDS ARE LESS HARMFUL IN COMPARISON TO CIGARETTES AND OTHER TOBACCO PRODUCTS

7. It is pertinent to note that ENDS do not contain tobacco, which essentially means that an ENDS user would still get their required dose of nicotine without having to ingest the 4800 chemicals contained in cigarette smoke. Moreover, E-liquids which are used in ENDS, are available in various nicotine strengths, from zero to higher levels. This helps an ENDS user to control their nicotine intake.

8. Further, a study conducted by the World Health Organization ("**WHO**") shows that tobacco smoking has been the cause for over 100 million deaths in the 20th century and is projected to cause

about 1 billion deaths in the 21st century. This study further states that the harm in tobacco cigarettes mainly arises from the tar and hot gases produced which are not present in ENDS. A copy of the article "E-cigarettes, vaping and public health" which incorporates the WHO study is produced as **Annexure D**.

9. Furthermore, studies by the Royal College of Physicians, London show that tobacco smoking alone was responsible for death of 122,000 adults in 2010 and has been found to cause lung cancer, chronic obstructive pulmonary disease and vascular disease. The same studies also look at ENDS in comparison and have identified them to be 95% safer than tobacco cigarettes. It further identifies chemical components such as Monamine Oxidase inhibitors, sugar, polysaccharides, flavorings, alkaline additives etc. as some of the additives used in tobacco cigarettes. These additives increase dependence on tobacco cigarettes, increase the speed of nicotine absorption, manipulate enzyme production and when inhaled at levels such as in tobacco cigarettes can be carcinogenic in nature. Moreover, flavouring agents in tobacco cigarettes are 110 times higher than those in ENDS and these flavouring agents cause manipulation of the CYP2A6 enzyme resulting in a quicker metabolism of nicotine. A copy of the research paper by the Royal College of Physicians on Nicotine without smoke and tobacco harm reduction is produced as **Annexure E**.

10. Extensive studies into the chemical composition of e-liquids in ENDS have shown that it contains a substantially lower number of chemicals in comparison to the thousands present in cigarettes. These studies also note that when it comes to flavouring, e-liquids show use of diacetyl, the chemical compound used in flavouring agents, at levels 110 times lower than in tobacco cigarettes. A copy of the article, 'The truth about Diacetyl', which points out the lower levels of Diacetyl in e-liquid is produced as **Annexure F**.

11. Also, studies conducted by Public Health England, shows that the main chemical ingredients used in ENDS are found in the e-liquid solution which is heated to generate vapor and this e-liquid has been identified as water, nicotine, propylene glycol, vegetable glycerine and typically also some flavouring. Further, this study incorporates the findings of the Independent Scientific Committee on Drugs that show that ENDS pose only 4% harm to the public and 5% harm to the user when compared with tobacco cigarette smoking. Lastly, this study, through data analysis of suicide attempts using e-liquids states that ENDS is rarely lethal and there is only one recorded fatality of a person who ingested over 10000 mg of nicotine. A copy of the Public Health England article – E-cigarettes, an evidence update is produced as **Annexure G**.

12. Further, a study conducted by Dr. Marina Murphy, Head of Scientific Media Relations, Research & Development at British American Tobacco, to compare the effects of smoke from tobacco cigarettes and vapor from ENDS based on stress, damage and disease caused to cells shows that tobacco cigarette smoke activates the stress response of the cells, causes double strand breaks in DNA and promotes formation of tumor. In comparison, ENDS showed no visible effects on the cells. A copy of the research report published by Dr. Marina Murphy is produced as **Annexure H**.

13. Lastly, ENDS devices, when tested to identify their effects on passive smokers, turned out to be eight times lower than the harm posed by tobacco cigarettes to passive smokers. It has also been found, in studies conducted by the Public Health England that ENDS release negligible levels of nicotine into ambient air, and leave significantly lower nicotine residue than tobacco cigarettes. A copy of the Public Health England article - E-cigarettes: a new foundation for evidence-based policy and practice, reflecting the effects of ENDS vapor to ambient air and passive smokers is produced as **Annexure J**.

14. ENDS devices provide to smokers a better and safer means of addressing their nicotine needs in public. Data from a study on the exhaled vapor from ENDS show that vapor from these devices undergo rapid decay and evaporation, lingering only for a matter of seconds unlike tobacco cigarette smoke which alters the composition of ambient air for a much longer duration. The copy of the Fontem Ventures study on exhaled e-cigarette vapor particles is produced as **Annexure K**.

15. Broadly, various studies have found that ENDS do not contain most of the chemicals found in tobacco cigarettes. These studies also find that chemical constituents that are common in tobacco cigarettes and ENDS appear to be of a substantially lesser quantity in ENDS. A copy of these studies has been produced as Annexure C, Annexure D and Annexure F above.

16. In light of the above, it is stated that ENDS provide an opportunity to tobacco cigarette smokers to reduce exposure to harmful tobacco smoke by substituting it with a far less harmful way of consuming nicotine. Nicotine is a relatively non-toxic substance and is not a direct cause to any smoking related illness. In fact, the key to reduction of harm caused by tobacco is eliminating inhalation of combustion products generated when tobacco is burned at high temperatures, as in tobacco cigarettes. It is these toxicants that are responsible for the majority of the serious health risks associated with tobacco cigarette smoking.

ENDS ARE AN EFFECTIVE DEVICE FOR TOBACCO CIGARETTE DE-ADDICTION

17. Smoking is a very difficult addiction to break. Studies have shown that approximately 80% of smokers who attempt to quit on their own relapse with the first month of abstinence and only 5% are successful in quitting smoking. Supporting smokers to quit as soon as possible is one of the most urgent priorities in healthcare. In this regard, a copy of the article published in the National Center of Biotechnology Information - Successful smoking cessation with electronic cigarettes in smokers with a documented history of recurring relapses: a case series, is produced at **Annexure L**.

18. Research has proved that addiction to nicotine is directly related to nicotine delivery speed. ENDS have a slow rate of nicotine delivery but can over a longer period of time deliver the same nicotine dose as a tobacco cigarette. Additionally, ENDS are highly non-addictive and very effective in smoking cessation. A copy of the article elaborating on the nicotine delivery speed in ENDS has been produced as Annexure D above.

19. Further, Scientists from the University of Patras-Greece, Onassis Cardiac Surgery Centre-Greece and the French National Research Institute for Health and Medical Research analyzed the data from the 2014 Eurobarometer on smoking and the use of the electronic cigarettes. Studies were conducted by principal investigator Dr. Farsalinos, on efficiency and popularity of ENDS in quitting tobacco cigarette smoking shows that ENDS have helped over 6 million users to quit tobacco cigarette smoking and over 9 million users to reduce the tobacco consumption in the European Union (“EU”) alone. A copy of the press release suggesting the above released by the University of Patras-Greece with regards to the study conducted by Dr. Farsalinos containing the data on efficacy and popularity of ENDS and its effect on smoking cessation is produced as **Annexure M**.

20. Contrary to the reasons stated by the Respondent in the Circular for banning the manufacture, sale and use of ENDS, research and data analysis shows that ENDS is used mainly by smokers with the intent to quit smoking or by people who have quit smoking with the intent to refrain from smoking. The data also shows that there are very negligible numbers of the youth and non-smokers who try ENDS. Further, it can also be seen that the majority of the youth and non-smokers who try ENDS do not show repeated use. The data further evidences that 72% of ENDS users use an e-liquid solution with nicotine content lesser than 4 mg/ml a day, which is far lesser than the nicotine content in traditional tobacco cigarettes. A copy of the ASH report on use of e-cigarettes among adults in England is produced as **Annexure N**.

21. Research shows that ENDS products have today become England's most popular aid to quitting smoking. ENDS have also been seen to play a unique role in the realm of mental health care as well, ushering in an opportunity to create mental health units that are not only smoke-free but also effectively help tobacco cigarette smokers to quit. The copy of the article stipulating the popularity of ENDS in England and their potential use in mental health care is produced as Annexure F above.

22. Furthermore, ENDS devices have been found to be more effective than nicotine replacement therapy as these devices induce an imitation of the mannerism used in smoking a tobacco cigarette. The copy of the article citing reasons for popularity of ENDS has been produced as Annexure D above.

23. The ban on use and sale of ENDS by the Respondent in Karnataka is therefore arbitrary and is not backed by any sound scientific reasoning or logic. It is also based on an unscientific and unreasonable classification and does not treat products similarly situated equally (nor users of such products). Further, the ban is disproportionate to the result aimed to be achieved *vide* the Circular. Also, it is in violation of the fundamental rights guaranteed under the Indian Constitution.

GROUND

24. The action of the Respondents is clearly arbitrary and unreasonable and hence violative of the provisions of Constitution of India. The actions of the Respondents have to be in conformity with principles of reasonableness and non- arbitrariness and it is expected to act only in furtherance of public interest. The actions of the Respondent in banning the manufacture, sale and use of ENDS is illegal, arbitrary, ultra vires and suffers from non-consideration of relevant material.

25. The Respondent is "State" within the meaning of Article 12 of the Constitution of India and is therefore expected to act in a fair and reasonable manner. The action of the Respondent in banning the manufacture, sale and use of ENDS without a reasonable justification is clearly arbitrary, unreasonable and hence falls foul of the Constitutional responsibility of the Respondent to act in a fair and just manner.

26. The Circular is in violation of Article 14 of the Constitution which requires that everyone be treated equally in the eyes of law and be subject to *intelligible differentia*. The differentiation must have a rational relation to the object sought to be achieved. The Supreme Court has evolved two tests to determine when Article 14 is violated. The first test requires that a classification be based on logical reasoning and bear a rational nexus with the intended object. The second test requires that the action taken by the State must be backed by sound logic and reasoning and not be arbitrary. The classification in the present case does not satisfy these tests.

27. The Respondent in this Circular has failed to take into consideration relevant material available and has discriminated between the users of tobacco cigarettes and users of ENDS without any reasonable justification. As stated above, the reasoning behind the ban of use and manufacture of ENDS stated in the Circular is that the nicotine contained in the e-liquid contained in ENDS is addictive and detrimental to health. However, the research and studies conducted (as narrated above) evidence that tobacco cigarettes are far more detrimental and addictive to human beings than ENDS. Further, tobacco cigarettes also cause harm to the environment. In contrast, ENDS are not only less harmful to human health, but also an effective means of de-addiction from smoking. Thus, it would be trite to state that, the Circular makes an unreasonable classification between ENDS and tobacco cigarettes and producers of ENDS and of tobacco cigarettes without any reasonable justification. Also, there is no nexus between the ban imposed and the object sought to be achieved by the Respondent. Hence, the Circular is in violation of Article 14 of the Constitution.

28. Further, the action of ban of manufacture, sale and use of ENDS is in violation of Article 19(1)(g) of the Indian Constitution. Article 19(1)(g) of the Constitution of India confers the right to practice any profession or to carry on any occupation, trade or business to all citizens. The State only has a right to impose reasonable restrictions in public interest. The Supreme Court of India has stated that the restriction imposed should not smack of arbitrariness. The Supreme Court of India has further stated that for the purpose of determining reasonableness, the nature of the right alleged to have been infringed, the underlying purpose of the restrictions imposed, the extent and urgency of the evil sought to be remedied thereby, the disproportion of the imposition, the prevailing conditions at the time, should all be considered. It has also stated that imposition of reasonable restrictions and its extent would depend upon the object

which they seek to serve. Lastly, the Supreme Court has laid down that the principles of proportionality and restraint are to be kept in mind to decide whether or not an action taken by the State can be adjudged as a reasonable restriction.

In the case of *Chintaman Rao Ram Krishna v. State of Madhya Pradesh* AIR 1951 SC 118, the Supreme Court has held that:

“The question for decision is whether the statute under the guise of protecting public interests arbitrarily interferes with private business and imposes unreasonable and unnecessarily restrictive regulations upon lawful occupation; [...] Unless it is shown that there is a reasonable relation of the provisions of the Act to the purpose in view, the right of freedom of occupation and business cannot be curtailed by it.

The phrase "reasonable restriction" connotes that the limitation imposed on a person in enjoyment of the right should not be arbitrary or of an excessive nature, beyond what is required in the interests of the public. The word "reasonable" implies intelligent care and deliberation, that is, the choice of a course which reason dictates. Legislation which arbitrarily or excessively invades the right cannot be said to contain the quality of reasonableness and unless it strikes a proper balance between the freedom guaranteed in article 19 (1) (g) and the social control permitted by clause (6) of article 19, it must be held to be wanting in that quality.”

29. In light of the above, the Circular issued by the Respondent banning the manufacture, use and sale of ENDS falls foul of Article 19(1)(g) of the Constitution of India. Primarily, the Circular states that the nicotine contained in the e-liquid contained in ENDS is addictive and detrimental to health. However, the research and studies conducted (as narrated above) evidence that tobacco cigarettes are far more detrimental and addictive to human beings than ENDS. Further, tobacco cigarettes also cause harm to the environment. In contrast, ENDS are not only less harmful to human health, but also an effective means of de-addiction from smoking. Secondly, the Circular justifies the ban of ENDS by stating that ENDS have been sold without obtaining valid licenses from the appropriate authorities specified by law. However, it is pertinent to note that the ENDS industry is unregulated in India and no regulations have been framed to enable licensing of such products. In these circumstances, the proportionate and reasonable course of action would have been for the Respondent to regulate and provide rules and regulations for the manufacture, sale and use of ENDS. A blanket ban on manufacture, sale and use of ENDS in Karnataka is unreasonable, without logic and disproportionate to the object that the Circular intends to achieve.

30. Additionally, it is submitted that, the Respondent has itself in the Circular stated that nicotine is allowed as an aid for de-addiction in nicotine replacement therapy under Drugs and Cosmetics Act 1940. It has failed to appreciate the fact that ENDS is highly effective and non-addictive method of smoke cessation. It is reiterated that the addiction to nicotine being directly related to the nicotine delivery speed. ENDS have a slow rate of nicotine delivery as compared to a tobacco cigarette, but deliver the same total nicotine dose as a tobacco cigarette over a long period of time, which helps in satisfying the nicotine craving without having to ingest the 4800 chemicals contained in tobacco smoke and in-turn help in reducing actual smoking. This makes ENDS an effective device that would help in smoking de-addiction. Further, traditional smoking de-addiction treatments include behavioral support and medications such as nicotine replacement therapies (NRT, nicotine patches, gums, inhalators, lozenges, nasal sprays, etc.), bupropion and varenicline, etc. All these are effective treatments, however, the success of these treatments for long term smoking cessation have proven to be low. Whereas, ENDS aim at harm reduction which provides users with the opportunity to reduced exposure to harmful tobacco smoke by substituting it with less harmful way of nicotine consumption and is also cost effective. Moreover, as narrated above, the studies on efficacy and popularity of ENDS have shown that ENDS have helped over 6 million to quit tobacco cigarette smoking and over 9 million users to cut down on tobacco consumption altogether in EU alone.

31. Further, the Circular issued by the Respondent banning the manufacture, use and sale of ENDS is in violation of Article 21 of the Constitution of India. Article 21, not only guarantees right to life but also confers right to life with dignity. A smoker has a right to a dignified life wherein he has an option to choose a less harmful alternative to traditional tobacco cigarettes. The Respondent by imposing a ban on the manufacture, sale and use of ENDS in the State of Karnataka has taken away the right available to smokers in Karnataka to use ENDS instead of tobacco cigarettes. As narrated above, smoking tobacco cigarettes is more harmful than using ENDS. Therefore, by banning ENDS, the Respondent has taken away the right of a smoker to live a more dignified and healthier life.

32. It is pertinent to clarify that, the Petitioner herein is neither contending that ENDS is not harmful nor denying the fact that nicotine is not harmful in nature. However, it is less harmful than tobacco cigarettes and is often used as an integral part of a de-addiction programme for nicotine and tobacco addicts. It is therefore essential that the use, manufacture and sale of ENDS be regulated in the State of Karnataka rather than be banned outright. The Respondent can establish various rules, regulation and guidelines to regulate the manufacture, sale and use of ENDS like the EU's Tobacco Products Directive. The Respondent can regulate the nicotine content and the use of other chemical in the e-liquids. Further, the State can various quality standard for e-liquids, which will ensure that no low-quality e-liquid containing harmful chemicals in sold in the State of Karnataka. Similarly, the Respondent can also establish various rules, regulation and guidelines for the ENDS device itself. This would help the Respondent achieve the object that it intended to in the Circular without having to impose a blanket ban on the manufacture, sale and use of ENDS.

33. The Petitioner reserves the liberty to urge such additional grounds as may be found necessary at the time of hearing the above writ petition.

34. The Petitioner has not filed any other writ petition on the present cause of action before this Hon'ble Court or any other fora.

GROUND FOR INTERIM RELIEF

35. The Petitioner prays that an interim order restraining the Respondent from implementing the Circular issued by the Respondent banning the manufacture, use and sale of ENDS pending a final decision in this writ petition be granted on the following among other grounds:

36. The Circular issued by the Respondent banning the manufacture, use and sale of ENDS is illegal, unreasonable, disproportionate to the object intended to achieve and arbitrary for the various reasons set out in the earlier sections of this petition. The Petitioner has a prima facie case and the balance of convenience is also in their favour. No loss or injury, much less irreparable loss or injury will be caused to the Respondent, if the interim prayer as sought for by the Petitioner, is granted.

37. In the event the interim relief prayed for is not granted the users of ENDS who are using it for the purpose of smoking cessation would be gravely affected as they wouldn't have an effective and accessible alternative for the purpose of smoking cessation. Further, the various manufacturers of ENDS would suffer grave losses due to shut down of their manufacturing units and loss of profits and this would in turn deny users of ENDS access to such a product. On the other hand, if the order prayed for is granted, the Respondents will not suffer any loss.

FINAL RELIEF

WHEREFORE it is most humbly prayed that, for the reasons set out above, this Hon'ble Court may be pleased to:

- i. Issue a writ of certiorari quashing Circular HFW/126/CGE/2016 dated 15 June 2016 issued by the Respondent ("Circular"), produced as **Annexure A**;

- ii. Issue a writ of mandamus directing the Respondent to permit the use sale and manufacture of Electronic Nicotine Delivery Systems ("ENDS") if necessary by framing necessary regulations for this purpose;
- iii. Constitute a committee with expert panel to conduct a proper research/study/analysis of ENDS and thereafter formulate rules, regulations and guidelines for use and sale of ENDS in Karnataka;
- iv. Award costs of the Petition; and
- v. Pass such further or other orders as this Hon'ble Court may deem fit and proper in the circumstances of the case and thus render justice.

INTERIM RELIEF

Pending the disposal of the present Writ Petition, the Petitioner prays that this Hon'ble Court may be pleased to:

- i. Stay the operation of the Circular HFW/126/CGE/2016 dated 15 June 2016 issued by the Respondent ("Circular"), produced as **Annexure A**;
 - vi. Direct the Respondent to permit the use sale and manufacture of Electronic Nicotine Delivery Systems ("ENDS") and refrain from invoking the Circular;

Place: Bangalore
Date: 22nd August 2017