



**GASP**

7 Cedar St., Suite A  
Summit, NJ 07901  
Phone: 908-273-9368  
Fax: 908-273-9222  
Email: [info@njgasp.org](mailto:info@njgasp.org)  
[www.njgasp.org](http://www.njgasp.org)

August 8, 2014

Division of Dockets Management  
HFA-305  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products

**Docket No. FDA-2014-N-0189**

Dear Commissioner Hamburg:

Global Advisors on Smokefree Policy (a.k.a. NJ GASP, Inc.) is pleased to submit our comments to the U.S. Food and Drug Administration ("FDA") on the proposed FDA deeming regulation that would expand the FDA's jurisdiction over tobacco products and electronic smoking devices.

Global Advisors on Smokefree Policy is a 40-year old nonprofit focused solely on tobacco control and prevention initiatives since its inception. As Executive Director, I have more than 20 years of expertise in emerging trends and issues in tobacco control, most recently regarding the health concerns with the use of, and exposure to vapors/smoke from, electronic smoking devices and hookah.

Our Policy & Legal Resource Center serves as a lead resource provider of educational technical assistance to policymakers stateside as well as on the global level. Most recently, Global Advisors on Smokefree Policy was the lead nonprofit agency to provide educational technical assistance to New York City Councilman James Gennaro who sponsored both city laws to (1) increase the age of tobacco and electronic smoking devices sales to age 21, and (2) ban the use of electronic smoking devices anywhere smoking is banned by city law, both inside and outdoors in all city parks and recreational areas.

In NJ, our Policy and Legal Resource Center served as the lead educational technical assistance resource provider for state laws that were first in the nation:

- Banning the use of electronic smoking devices wherever smoking is banned

in public places and workplaces (2010);

- Banning smoking in college dormitories (2005);
- Increasing the age to 19 for sales of tobacco (2006); and
- Implementing a ban on flavored cigarettes (except menthol and clove)(2009).

New Jersey is poised to be the first in the nation to ban smoking in all public parks and recreational areas (state, county and local), including the use of electronic smoking devices. The State Senate also passed by a 2/3 vote a law to increase the age of tobacco and electronic smoking device sales to age 21, with this bill expected to be heard in the Assembly Health Committee in the autumn.

The breadth and depth of our experience and expertise in tobacco control policy gives us the opportunity to share our suggestions as to what next steps should be taken with regards to an FDA regulation of tobacco products and electronic smoking devices.

1. It is important to have parity amongst all tobacco products and electronic smoking devices, when it comes to (1) banning the same flavors for all products, (2) banning self-service displays and sales of all products, (3) taxation of all product, (4) licensing of all product sales, and explicitly stating that federal law will not preempt stronger local, county or state laws.

Without parity on these 4 key points, users will switch to lower priced products, products with easier access, or products that are appealing in flavorings that are still allowed in some products but not others. Research has shown the inverse relationship between tobacco taxation and product use, so it is imperative that federal tax rates on all tobacco products and electronic smoking devices are at least equal to the federal tax on cigarettes, in order to equally reduce the rates of usage for all tobacco products and electronic smoking devices.

For instance, the current FDA regulations only ban self-service displays of certain tobacco products but not all tobacco products or electronic smoking devices. The definition of "tobacco products" in the proposed regulations does not have premium cigars in the same category. Tobacco is the #1 cause of preventive disease and death in our nation and the world. There is no reason to provide special dispensation to specialty tobacco industries for their products, which can do equal or greater harm to the user and innocent bystander who intakes the secondhand smoke.

2. It is imperative that there is strong "no preemption" language in the regulation, due to the fact that the most progress on regulating and restricting tobacco products and electronic smoking devices is at the local, county or state levels. New Jersey was the first state to ban the use of electronic smoking devices inside public places and workplaces, and this law should not be preempted by any federal law that is weaker or equivalent to,

since local enforcement is key to ensuring compliance.

3. The electronic smoking device industry's initial branding and marketing is that of a smoking cessation device. Even with FDA warnings to the industry about not advertising or marketing their products as smoking cessation devices, the industry continues to indirectly accomplish this marketing. Electronic smoking devices should only be on the market if each manufacturer can pass the rigorous FDA drug application process, similar to how other nicotine replacement therapy smoking cessation devices are required to do so. Semantics employed by the electronic smoking device industry should not dictate classifying their products as "tobacco products". For all intents and purposes, these products are on the market to serve as a smoking cessation device, and should be regulated as such, not as a "tobacco product".

There are enough studies to demonstrate that electronic smoking device usage, and exposure to the vapors is, in the immediate and short-term, hazardous to health. See our white paper on these health concerns at <http://www.njgasp.org/e-cigarettes-other-tobacco-products-otps/electronic-smoking-devices-e-cigarettes/>

In addition, personally in-taking high levels of electronic smoking device secondhand vapors at the NYC City Council hearings, where testimony was provided for the bills to ban such products in workplaces, public places and outdoor recreational areas, caused immediate deleterious health effects to myself and colleagues. Based on the wealth of research on the health hazards from cigarette smoking and exposure, one can assume that there will be long-term health concerns and effects with electronic smoking devices, due to the fact that immediate and short-term hazardous health effects are already documented.

Marketing and advertising restrictions of electronic smoking devices need to be equivalent to current cigarette requirements.

In conclusion, a 'precautionary principle' should be employed that bans electronic smoking devices until proven to be safe as an FDA approved smoking cessation device, rather than risk addicting a nation to a product that may be equal to, or even more harmful than, conventional tobacco products.

Respectfully submitted,

*Karen Blumenfeld, Esq.*

Karen Blumenfeld, Esq.  
Executive Director  
Global Advisors on Smokefree Policy