At the September 24, 2014 IQPC ECig USA Industry Conference in Las Vegas, I opted to abandon my previously anticipated presentation in favor of the following, based on presentations and dialogue earlier that day. After a personal introduction and disclaimer, I presented the following:

A Modest Proposal to the E Cigarette Community

1. For reasons having to do with the FDA process and major differences between stakeholders as to how E Cigarettes (EC) should be regulated by the FDA, I estimate that it will be **at least four years, and possibly as long as ten years before FDA will be in a position to implement regulations having to do with the manufacture and marketing of e-cigarettes**. This being the case, it would be a losing strategy for the EC community to simply wait to see what FDA will do. Instead, I recommend that the EC community conduct a major research, policy development and advocacy initiative for the purpose of proposing to FDA what the industry believes would be appropriate regulations, and to secure the support of elected officials and others for the proposed regulations. This would best be done by working through membership organizations representing manufacturers, vendors and vapors (SAFTA, TMA, CASAA, and possibly others) and others in the EC community who can openly discuss the benefits of EC use without incurring the wrath of FDA for claiming tobacco harm reduction (THR) and cessation benefits.

2. The major problem with the **FDA, NIH and CDC** approach and research agenda to date is that it has been **entirely negative** with regard to THR and E cigarettes. They have considering only potential harms, but **not the well-documented potential benefits** of incorporating a THR component to current tobacco control programming. This would include e-cigarettes as a prominent, but not the only harm reduction modality. Once that is done, the federal agencies can then approach EC from the perspective of how best to maximize public health benefits while minimizing harms. Such **benefits have not been considered to date by the federal advisors and decision makers** since there is no precedent for considering possible benefits of any non-pharmaceutical nicotine delivery product and since such consideration would appear to conflict with their long-term goal of a "tobacco-free-society." Ironically, available evidence strongly suggests that the most effective way to move us in the direction of an eventually tobacco-free society would be to encourage current smokers to switch to products like EC that are less addictive and easier to quit..

3. Not only are **ECs** less harmful than cigarettes, they are also **less addictive and easier to quit**. Both the harm and addictiveness of a tobacco-related product are primarily based on whether they are absorbed through the **mouth, trachea or pulmonary alveoli** (the small air sacs in the lung where O_2 and CO_2 are exchanged). Risk and addictiveness are maximal for tobacco cigarettes, where toxic particular material, with nicotine attached are lodged in the alveoli, and remain there until fully absorbed by the body. ECs are intermediate in risk and addictiveness since there is no solid particulate matter and the vapor is absorbed in the trachea and major bronchi. Here the tissue is less sensitive, and the trachea and bronchi are continually self-cleaning,

so the residue of the vapor slowly but consistently cleaned out from these sites. Smokeless whole tobacco products are primarily absorbed through the oral mucosa, a tougher tissue that is continually bathed in saliva. *(Please note that this explanation is both oversimplified and extrapolated from available literature and knowledge of oral and pulmonary physiology. Differences in addictiveness are well documented)*

4. If THR is to have maximal public health benefits, with minimal adverse consequences, it needs to be done on a **partnership basis with manufacturers, vendors, vapors and other EC advocates working hand in hand with public health authorities**. Given the entirely negative attitude toward EC by current public health authorities, development of such partnership will depend on the generation of convincing research, development of policy recommendations, plus **advocacy on behalf of ECs, primarily with and through influential academics and federal and state legislators**.

5. Finally, the industry and other EC advocates should play the lead role in **proposing standards for EC manufacturing and marketing**. In this regard, several items stand out as deserving special attention. The first is the **maximal allowable dose per ml of nicotine in EC fluid**. If the smokers we would most like to reach are the heaviest smokers, then high doses of nicotine in the EC fluid may be needed to enable them to switch to ECs. Second is the issue of **flavoring.** Here we must consider both the attractiveness of the fruit and candy flavors to adults, especially those 19-35 years of age, as compared to their attractiveness to minors. Such flavoring appears to be critical to attracting and retaining young adult smokers away from tobacco cigarettes. The third item in this regard is **marketing** – and consideration of what marketing guidelines would best attract adult smokers, and whether there are specific marketing practices that have been proven to attract teens and other non-smokers to continuing EC use. It would appear that marketing, not the chemical makeup of the EC fluid, which determines attraction to non-smokers relative to experimentation and/or continuing EC use.

In conclusion, I urge a major initiative to take advantage of the four to ten years before FDA implements EC regulations. This initiative should take the form of manufacturers, vendors, vapors and other EC advocates working through their membership national organizations and consultants to do the research, policy development, and advocacy needed to convince federal authorities to both implement optimal regulations and add a THR component to current tobacco control programming. The purpose of this enterprise would be to achieve public health benefits not otherwise achievable, and do so while minimizing potential harms.

For additional detail and bibliographic references, please see: http://www.mdpi.com/1660-4601/11/6/6459 and http://www.rstreet.org/wp-content/uploads/2014/07/20140630FDLI-EcigForum.pdf

Please note that these remarks represent the personal/professional opinion of Dr. Nitzkin, and do not represent established policy or perceptions of any organization that I am or have been affiliated with. Joel L. Nitzkin, MD; jln@jln-md.com