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Nude Nicotine & N.N. Analytics Corporate Statement – Addressing the "Vaping Illness" – Acute Lung Failure & Lipoid Pneumonia

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My name is Jake Rubenstein. I am blessed and privileged to be able to submit a written statement on behalf of my manufacturing facility Nude Nicotine, analytical laboratory N.N. Analytics, and regulatory consulting agency eLiquid GMP. I am here to speak proudly, boldly, and without reserve, on behalf of my colleagues in the scientific community and our collective research teams involving Electronic Nicotine Delivery Systems (ENDS – FDA terminology) here at Nude Nicotine & N.N. Analytics in San Diego. We, and our partner stakeholders, take tobacco control very seriously – when a product, service, or message is a detriment to public health, we feel it our mission to research, inform, discuss, and react in a collective manner. This is not only the scientific method, but a healthy approach to public policy. When the comments associating the "Vaping Illness" arose with correlations to flavored tobacco products, especially in those cases involving minors, we felt immediate action was necessary.

Inhalation Toxicology is one of Nude Nicotine's (and other valuable stakeholders in the tobacco science sector) core competencies. Many outside the tobacco industry do not realize this fact – the data is in its conclusions are clear – flavors used in validated and FDA-reviewed eLiquids do not contain compounds, or levels of compounds, deemed harmful to the appropriate Protection of Public Health (APPH – FDA terminology) by inhalation at normal usage rates. Not only do our customers products contain extensive toxicological data for inhalation of their products by computer modelling, but many, if not most of them, have begun to endure the rigorous journey of independently-reviewed (IRB-approved) clinical trials on their products in humans to prove these facts. These demands are mandated by the FDA for market authority in the US by May 2020 under the Pre-Market Tobacco Application (PMTA) program.

Parents, teachers, and community leaders were rightfully outraged – the flood of broadly-classified news reports in combination with the CDC's initial reports of the "Vaping Illness" linked to all vapor products sent the public into damage-control mode. Some considered this a "public health crisis" and rightfully so. There are friends and loved ones who will no longer be with us due to their inhalation of substances from THC and CBD vapor products. I, our partners, and the entire community, mourns these losses, and are equally frustrated at the public for not having proper control measures in place to test for, control, and enforce against THC and CBD companies selling these products. From one viewpoint, we must applaud the public health officials' and governments willingness to address the

issue – for us stakeholders, we are appreciative of the ability to address core issues of tobacco control – our missions are aligned wholly in this manner. However, our frustration has peaked over an even more toxic issue – the "bundling" of two equally important, but separate issues – tobacco control and the "Vaping Illness." From this other viewpoint, we must protest the hasty way decisions were made. When honest, scientifically-transparent companies like many in the ENDS industry, are bundled with illicit cannabis and hemp companies as the cause of the "Vaping Illness," they (and we) will not stand idly by. These companies, mostly small to medium sized businesses, not tobacco corporations, will not stand for this categorization of their products, or intent of their business.

Public policy is, and always has been, driven by subject-matter-expert review, and with proper impact studies prepared to demonstrate the effectiveness of the public policy. This "Vaping Illness" is not, has never been documented to, or will never be the result of, minors' access to tobacco products. The media's failure to address the scientific literature of the real issue at-hand – and even more damaging, replacing it with tobacco control issues like minors' access to tobacco products, has truthfully, disabled the public's ability to allow for proper public policy related to tobacco control. All vested stakeholders will agree with the following statement – "flavored tobacco products should never be sold in a location with exposure to, or directly to, children under the legal smoking age." However, now that the public's most trusted officials, their public health departments, have been fed broad statements by the CDC and poorly educated health "professionals" and public policy "experts." A community-driven approach was not taken. The data was not reviewed to address the source of the "Vaping Illness," resulting in poor public policy that will not stop the hemp and cannabis companies producing products with these harmful or potentially harmful chemicals (HPHCs – FDA terminology).

eLiquid products containing nicotine, historically, have never used non-polar components to the water-soluble chemistry of the solution. These compounds' inhalation toxicology is well known to the medical literature as GRAS for inhalation, with most critical data being publicly available over a decade ago. No acute illness, known to the medical literature, had been ascribed to (an) ingredients used by vaporization, especially not one affecting over 1000 patients. Prior to 2019 there were very few adverse effects, even as the electronic industry grew to its first peak in 2015. The few isolated cases were traced to exposure to an e-liquid that was not manufactured to proper standards. However, in the summer of 2019, a large amount of lipoid pneumonia cases began to appear in patients who were known "vapers." Upon closer clinical, radiological, and sometimes pathological scrutiny, these patients had been exposed to lipids not found in traditional e-cigarettes with nicotine, but from cannabis and hemp oils with adulterants.

It had become clear that the HPHCs connected to the cases of acute lung failure associated with vaping is linked to a new class of lipoid pneumonia, eVapor-Associated Lung Injury (EVALI) (5). These HPHCs - triglycerides, vitamins, and oils – are atomized in an electronic cigarette or vaporizer, most often from THC and CBD products. The sources of exposure of aerosol containing these contaminants can be attributed to the improper use of topical products labeled as "oils" in a vaporizer, or the

presence of these HPHCs in the product formulation itself. Hemp and Cannabis industry stakeholders do not test for, consider, or provide ingredients list disclosure of their products sold to consumers. These HPHCs are commonly added by the manufacture to "cut," dilute, and/or lower the cost of their final product while maintaining an oil-like consistency; they do so without regard to the potential adverse effects of the inhaled aerosol of these compounds.

"Vaping" or "Vapor" can constitute many products, including ENDS, THC vaping products, CBD vaping products, untested holistic therapies, and black-market products of many variants. This information was revealed in patient case studies from hospital networks as-early-as August of 2019, but corroborated by the CDC on October 11th with the following statements:

- Most patients report a history of using tetrahydrocannabinol (THC)-containing products. The latest national and state findings suggest products containing THC, particularly those obtained off the street or from other informal sources (e.g. friends, family members, illicit dealers), are linked to most of the cases and play a major role in the outbreak (1).
- Therefore, CDC recommends that you should not use e-cigarette, or vaping, products that contain THC (1).

Nude Nicotine & N.N. Analytics recommend a community-driven approach to approach the federal government for resources and assistance – the CDC will directly-mediate to assist in the validation of scientific reasoning, public health impact statements, and will assist with minor and major cost factors. The "EPI-AID (2)" resource center is the Federal Government's "hotline" for issues like these – public health emergencies. States like Illinois and Wisconsin have both called upon this center for assistance. Both governments are now working diligently with the CDC and DEA to identify products, locate manufacturing operations, and arrest proprietors of illicit black/grey market CBD and THC vaping product operations. Another State, Colorado, not less than 48 hours ago, arranged a State Board of Directors hearing to meet with its Marijuana Enforcement Division (4). The state is in the process of finalizing the addition of vitamin-e, medium-chain triglycerides (MCT oil), and polyethylene glycol (PEG), three of these unhealthy diluents/adulterants, to the required list of analytes to-be-tested for in all vaping products. We can only applaud these three State's approaches to data-driven, and community-driven public policy, allowed to be commented on by all relevant parties, like the source of the EVALI itself – cannabis and hemp companies.

THC Vaping Products are regulated by State-run agencies, like the California Bureau of Cannabis Control (BCC) & Hemp products are not regulated in the same fashion but fall under the jurisdiction of California's Department of Food and Agriculture. We formally recommend communities to speak directly to the Cannabis Advisory Committee in their state on their responsibility in addressing the needs of additional analytical testing, enforcement, and future regulatory concerns. Surprisingly, the state-mandated analytical protocols do not mandate testing for these oil-soluble ingredients – it is their liability to educate their stakeholders and the public. Unfortunately, as of the last 60 days, it has fallen upon the ENDS-industry-stakeholders to bring light to this fact. In many states, a discovery of

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such information is mandated to be disclosed to the proper authorities for further action. In California, this is a mandated requirement of the Department of Food and Agriculture and the Department of Public Health under Business and Professions Code Section 26014.

As an industry stakeholder, Nude Nicotine & N.N. Analytics have a professional agenda to address the "Vaping Illness" with 1 immediate action item to address EVALI and 2 ongoing action items to address proper tobacco control policy:

Immediate: Proper Analytical Testing: All vaping products, whether containing nicotine, CBD, or THC, must be submitted for analytical testing by a 3rd-party laboratory to be sold to the public. This protocol is recommended to be added to the FDAs HPHC list, as defined in the 21 CFR Part 1100, as well as applied to any, and all inhalation products, as in cannabis products under state-regulated statutes.

Ongoing: Mediated Scientific Review: Local governments are recommended to hold both open and closed meeting sessions with all relevant stakeholders and the public able to submit comments. In addition, CDC-EPI and other federal government resources should be consulted on developing an effective policy, as well as make public the results of the impact study of the proposed policy.

Ongoing: Smart Tobacco Control and Public Health Policy: We recommend each government entity to evaluate the resources, locally, state-wide, and federal, to commit ENDS, cannabis, & hemp vapor businesses to register and maintain licensure to do business in the region. In addition, we recommend that the public comment on manners in which they would like to regulate the businesses, commit to taxation, and act in support of enforcement of unregistered products as well as their sale to adults of age. In order to facilitate an approach that is most effective in reducing rates of smoking and restricting access to minors, each proposed policy must be produced with a 3rd-party-reviewed impact study. Without an impact study, the political intentions of legislation and/or policy cannot be considered as impartial.

With kind regards,

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