ARENA
INTERNATIONAL EVENTS GROUP

NEXT GENERATION NICOTINE DELIVERY US 2023

Hilton Miami Airport Blue Lagoon, Miami, USA

28th-29th June, 2023

2023 Key Speakers:

Todd Cecil, Deputy Director for Regulatory Management, FDA
John O'Brien, Vice President and Assistant General Counsel - Regulatory, Reynolds American
Tony Abboud, Executive Director, Vapor Technology Association and President, Strategic Government Solutions
Dr. Jennifer H. Smith, Associate Fellow - Scientific Strategy and Advocacy, Altria Science
Sky Carman, Master Scientist, Reynolds American
Bonnie Herzog, Managing Director, Goldman Sachs
Travis Priddy, CEO, 369 Hemp, Inc.
Martin Steinbauer, Founder, SMOOD LLC
Catharine Dockery, Founder and GP, Vice Ventures
Samy Hamdouche, Cofounder and COO, Lucy Goods Inc.
Anuschka Merson, Director, Regulatory and Scientific Affairs, ITG Brands
Jeff Connell, CEO, Innevape Eliquids
Fadi Maayta, Co-Founder and President MEA, ANDS
Saadiq Daya, CEO, VanGo Vapes
Niraj Patel, CEO, Bidi Vapor
Tim Phillips, Managing Director, EcigIntelligence
Allison Boughner, VP, American Vapor Manufacturers Organization
Michael Saxon, Chief Executive Officer and Board Director, TAAT Global
Mark Dempsey, Global Consulting Director, Global Data
Eric Gotting, Partner, Keller and Heckman LLP
Dr. Jessica Zdinak, Chief Research Officer and Owner, ARAC
David DeJean, Head of Sales and Business Development, Systech International
Robert Burton, Group Scientific and Regulatory Director, Plxsur
Jerry Donnini II, Shareholder, Law Offices of Moffa, Sutton, & Donnini, P.A. & Founder of Tobacco Tax Refund, Inc
Peter Joza, Chief Scientific Adviser, Labstat
Shelly Blackwell, Senior Director for Dietary Supplement and Tobacco Services, EAS Consulting Group
Chris Allen, Chief Executive Officer, Broughton
Eric Heyer, Partner – Business Litigation and Regulatory, Thompson Hine
Joe Smith, Partner - Business Litigation and Regulatory, Thompson Hine
Dr. Vincent J. Angelico, Chief Scientific Officer, Accorto Regulatory Solutions
Ken Sickles, Executive Vice President, Chief Product Officer, Digimarc
Dr Cuie Yan, VP Encapsulation/Application, Blue California

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	DAY ONE, Wednesday 28th June 2023
08:00 - 08:50	Registration and refreshments
08:50	Chair's opening remarks ***Mark Dempsey, Global Consulting Director, Global Data***
09:00	**FDA process updates and things you need to know for new applications** • Leveraging long-awaited FDA feedback on submissions to be successful in reapplying • What is the tangible value of an MRTPA without healthcare provider outreach? • Strategies in post-market surveillance activities • Looking backwards to look forwards: Retrospective look at FDA tobacco and nicotine regulations ***Todd Cecil, Deputy Director for Regulatory Management, FDA***
09:30	**Session reserved for sponsorship**
10:00	**Current regulatory landscape and views from in-house counsel** • Need for more compliance and enforcement and increased clarity about what products can be lawfully sold • Potential impact and changes at CTP in response to the Reagan-Udall Foundation's Report • Upcoming rulemaking (e.g., menthol, VLNC) ***John O'Brien, Vice President and Assistant General Counsel - Regulatory, Reynolds American***
10:30	**Session reserved for sponsorship**
11:00	**Morning Refreshments and Networking**
11:30	**Addressing the contradictions of FDA and US regulatory policy on tobacco and nicotine** • Are FDA's response to serious criticisms of Reagan-Udall Foundation sufficient or appropriate? • Are current US regulatory approaches injurious to, rather than protective of, public health? • What is the role of science in driving FDA regulation and decisions on PMTAs? • What are potential policy and regulatory solutions to the apparent contradictions in science and US/FDA approaches to harm reduction? ***Tony Abboud, Executive Director, Vapor Technology Association and President, Strategic Government Solutions***
12:00	**FDA PMTA Deficiency Letters – Are you prepared?** • Where are we now – insight into the FDA PMTA review process • Defining your strategy – the art of good preparation • PMTA modules where deficiencies are most common • Finding the right partner for a successful response **Chris Allen, Chief Executive Officer, Broughton**

12:30	**Panel Discussion: What's happening in the rest of the world?** • Identifying opportunities for overseas growth • Comparing and contrasting approaches from around the globe • Global influences on the US nicotine market • Worldwide outlook on the burden of tobacco ***Chair: Robert Burton, Group Scientific and Regulatory Director, Plxsur*** ***Panel: Jeff Connell, CEO, Innevape Eliquids*** ***Michael Saxon, Chief Executive Officer and Board Director, TAAT*** ***Tim Phillips, Managing Director, EcigIntelligence*** ***Chris Allen, Chief Executive Officer, Broughton***
13:00	**Lunch and Networking**
14:00	**Youth vaping "Epidemic"** • Finding the balance; addressing youth marketing while ensuring vaping maintains its harm reduction status • Potential regulations to deal with youth vaping • Function of disposables or marketing; understanding is the key to prevent future negligence • Urging companies to review their marketing to make sure it is responsible • Understanding the difference between observations of facts and actual problems with solutions ***Saadiq Daya, CEO, VanGo Vapes***
14:20	**Getting into the minds and hearts of the consumer: how to use behavioral science from product development to product applications** • Do you know who your target consumer is and what they want? • What (and who) are the key roadblocks to switching adult smokers? • Are you designing your key Perception and Behavior PMTA studies to effectively address FDA's needs and concerns? • How can the social and behavioral sciences "save" flavors? ***Dr. Jessica Zdinak, Chief Research Officer and Owner, ARAC***
14:50	**Role of innovation to protect consumer** • ENDS industry made remarkable progress switching millions of adult smokers to potentially reduced-risk products • Despite all the challenges and mainly what Middle Eastern markets are facing, such as harsh fiscal, non-balanced regulation, illicit rage, and others, the ENDS industry is growing • A key issue we are facing today, beyond switching adult smokers, is targeting the WRONG group of consumers, such as non-smokers, ex-smokers, and minors, who are being attracted to many wrong innovations. • Industry needs to work together to find a solution to protect the WRONG group of consumers from accessing the category by exploring innovations and programs to protect the WRONG group of consumers from getting attracted to these products and making it difficult to have access to such products ***Fadi Maayta, Co-Founder and President MEA, ANDS***
15:10	**Full Court Press: Vapor Litigation Update** • Flavor Bans • FDA Refuse-to-Accept (RTA) and Refuse-to-File (RTF) Orders • Recent FDA Enforcement Actions and Consent Decrees • Challenges to FDA Marketing Denial Orders (MDOs) ***Eric Gotting, Partner, Keller and Heckman LLP***
15:40	**Afternoon Refreshments and Networking**
16:10	**Why isn't synthetic nicotine doing as well as predicted?** • Why are countless synthetic nicotine products being rejected by the FDA? • What have been the implications on business as FDA closes regulatory loophole?

	• Fostering a positive approach and benefiting from the opportunities the new regulations bring ***Anuschka Merson, Director, Regulatory and Scientific Affairs, ITG Brands***
16:30	**Panel Discussion: What the flavor restrictions mean for the future of nicotine delivery?** • Looking outward: can Australia's prescription-only model for vaping products be viable in the US? • Will the prohibition of menthol be detrimental to the progress the alternative nicotine delivery industry has made in helping smokers quit or will it serve the opposite effect? • Would total flavor prohibition be beneficial for tobacco control? ***Chair: Tony Abboud, Executive Director, Vapor Technology Association and President, Strategic Government Solutions*** ***Panel: Samy Hamdouche, Cofounder and COO, Lucy Goods Inc.*** ***Saadiq Daya, CEO, VanGo Vapes*** ***Bonnie Herzog, Managing Director, Goldman Sachs***
17:00	**Nicotine Addiction: Politics, The Media, Regulation, and Science** • Managing addiction using the risk continuum versus the unrealistic objective of cessation. • Traditional Tobacco versus Newly Deemed less harmful products - who should have greater access to the marketplace? • The Media, Special Interest Groups and Politicians driven misperceptions of the relative harm reduction of newly deemed products. • The CTP has failed in its implementation of a predictable path to market for safer nicotine delivery products while allowing hundreds of grandfathered product types to get to market via the substantial equivalence pathway. Why? ***Dr. Vincent J. Angelico, Chief Scientific Officer, Accorto Regulatory Solutions***
17:15	**Live Long Vapor - Our 10-year journey from a small Florida business to a worldwide brand** • The 'Wild West' early days of the e-liquid industry • Establishing a national brand - Setting the Standard • The World Stage - Trials and Tribulations of going global • Live Long Vapor - Our mission statement ***Jeff Connell, CEO, Innevape Eliquids***
17:35	**Chair's Summary and Close of Day 1**
17:45	**Drinks Reception**

	DAY TWO, Thursday 29th June 2023
07:50 - 08:20	**Registration and Refreshments**
08:20	**Chair's Opening Remarks** ***Mark Dempsey, Global Consulting Director, Global Data***
08:30	**Revolutionizing Innovation: The Harm Reduction Opportunity of Modern Oral Nicotine Pouches** • Role of modern oral nicotine pouches in tobacco harm reduction • Flavors as a motivator to switch for adults who smoke • The importance of a marketplace of FDA-authorized smoke-free products that satisfy adults who smoke ***Dr. Jennifer H. Smith, Associate Fellow - Scientific Strategy and Advocacy, Altria Science***
09:00	**Why harm reduction nicotine is the only investible category for the future of nicotine delivery** • Modern nicotine investing has nuance • Maximizing the potential of harm reduction nicotine • Investment insights on early-stage nicotine ***Catharine Dockery, Founder and GP, Vice Ventures***

09:30	**Roundtable 1:** Hosted by David DeJean, Head of Sales and Business Development, Systech International **Creating an industry-FDA collaboration to prevent illicit products, reduce youth use, and protect brands and consumers**	**Roundtable 2:** Hosted by Peter Joza Chief Scientific Adviser, Labstat and Shelly Blackwell, Senior Director for Dietary Supplement and Tobacco Services, EAS Consulting Group **Heated Tobacco and Modern Oral Products – Tobacco Product Manufacturing Practice (TPMP) Readiness and Premarket Tobacco Product Application (PMTA) Testing Challenges**	**Roundtable 3:** Hosted by Allison Boughner, VP, American Vapor Manufacturers Organization **How to keep up with changing consumer behavior**	**Roundtable 4:** Hosted by Enthalpy Specialty Labs
10:30	**Morning Refreshments and Networking**			
11:00	**Reducing the risks of inauthentic nicotine products** The global popularity of tobacco and the massive profits generated by cigarettes and other nicotine products attracts highly motivated counterfeiters. Fakes can have catastrophic consequences for producers ranging from harmful effects on consumers and an increased risk of lawsuits, to lost revenue, poor brand loyalty, and the scrutiny that results from lower tax proceeds. • Learn why the nicotine delivery market needs more sophisticated anti-counterfeiting solutions • Hear about how a major global tobacco producer is leveraging digital watermarks to secure the authenticity of its products • Understand what you can learn from pharmaceutical brands and central banks that use the same technologies to protect their integrity ***Ken Sickles, Executive Vice President, Chief Product Officer, Digimarc***			
11:15	**Navigating the FDA PMTA landscape from a device engineering perspective for next generation product submissions** • The PMTA pathway involving electronic devices according to the Final Rule • The PMTA Final Rule requirements for components, device design, specifications, and parameters • Product Design, Functionality, Testing, and Analysis of electronic devices for a PMTA ***Sky Carman, Master Scientist, Reynolds American***			
11:45	**Challenging the tax man: an update on state tobacco and vape tax issues and refunds** • Recap of successful state tobacco tax refunds and savings • Common state tax audit pitfalls • Future vape and tobacco refund opportunities • State licensing issues ***Jerry Donnini II, Shareholder, Law Offices of Moffa, Sutton, & Donnini, P.A. & Founder of Tobacco Tax Refund, Inc***			
12:00	**FIRESIDE CHAT** **Unlocking the potential of herbal tobacco amidst regulatory changes to flavors** • Herbal tobacco as a catalyst for the whole sector to start moving again since slow FDA product approvals • Critical appraisal of clinical trials assessing heated tobacco products: Latest scientific findings on the impact on public health • Capitalizing off the growing popularity preparing for new era of herbal tobacco products • Has the herbal tobacco industry overcome the necessary regulatory hurdles to be a sustainable solution to end smoking? ***Michael Saxon, Chief Executive Officer and Board Director, TAAT***			
12:20	**Lunch and Networking**			
13:20	**Using consumer insights to understand future opportunities** • The claims, ingredients and flavours driving consumer engagement. • Understanding and leveraging ethics and ethical decision making • Identifying how the younger consumer (21-30) makes decision today.			

	Mark Dempsey, Global Consulting Director, Global Data
13:40	**The conscious smoker in the modern world: growing hemp to grow business** • Getting excited for the future of hemp • Managing the accelerating change in smokers' habits • Capitalizing on opportunities in the untapped hemp market • What the hemp boom means for the legalization of cannabis? ***Travis Priddy, CEO, 369 Hemp, Inc.***
14:00	**Session reserved for sponsorship**
14:30	**Panel Discussion: Where is the cannabis industry headed?** • Hear about latest regulatory updates on CBD, Delta-8, and hemp-derived products • Assessing the marketability of cannabis products and how it will affect the nicotine industry • Dispelling doubts and concerns of unreceptive consumers • Delving deeper into implications of legalizing cannabis and reducing access to black market ***Chair: Mark Dempsey, Global Consulting Director, Global Data*** ***Panel: Travis Priddy, CEO, 369 Hemp, Inc.*** ***Dr Cuie Yan, VP Encapsulation/Application, Blue California*** ***Eric Heyer, Partner – Business Litigation and Regulatory, Thompson Hine*** ***Joe Smith, Partner - Business Litigation and Regulatory, Thompson Hine***
15:00	**Afternoon Refreshments and Networking**
15:30	**Session reserved for sponsorship**
15:45	**State of Vape: A focus on legal-age smokers** • Sharing best practice of successful marketing to grow business and reducing damage to the youth initiation • Finding the balance: addressing youth marketing whilst ensuring flavored products remain available to adults • Function of the disposable or marketing: understanding this is key in prevention of future negligence • Urging companies to spearhead initiatives to crack down on youth initiation ***Niraj Patel, CEO, Bidi Vapor***
16:05	**Upcoming Research on Quantifying Carbon Emissions and Recycling Rates for ENDS** • Examining the current state of ENDS manufacturing and disposal: the lifecycle of nicotine, hardware, batteries in various ENDS categories • Conducting a landscape review of ENDS recycling, highlighting industry participants, and described by comparison to other FMCG industry recycling practices • Quantifying consumer recycling habits of ENDS in various jurisdictions as well as the propensity of ENDS users to recycle before and after implementation of a recycling program. • Creating a Recycling Model Framework using findings and best practices from this research for dissemination across industry and government ***Martin Steinbauer, Founder, SMOOD LLC***
16:25	**Harpooning Leviathan: Ways and Means to Hold Regulators and NGOs Accountable** • FDA knows that vaping is a low-risk, effective quit-smoking tool • FDA's doubletalk • Reporters fail to hold FDA accountable • Solutions ***Allison Boughner, VP, American Vapor Manufacturers Organization***
16:45	**Chair's Summary and Close of Conference**