



## Evidence-Based Science, Electronic Cigarettes & Tobacco Harm Reduction

Williamsburg IX  
May 19 - 22, 2014  
Kingsmill Resort, Williamsburg, Virginia

[James River Ballroom & Prefunction](#)

### Monday, May 19<sup>th</sup> - Deeming Regulations

12:00 PM     Boxed Lunch

12:30 PM     **Welcome and Conference Overview (Farrell Delman, TMA)**

12:45 PM     **Deeming Regulations**: Initial Impressions by Product Sector

*Session Moderator: **Rob Wilkey, JD, MPH** (Commonwealth-Altadis & TMA Chairman)*

#### ***Large Cigars***

Altadis (**Barry Schaevitz, JD**, Jacob, Medinger & Finnegan)  
Scandinavian Tobacco Group US (**Daniel McGee, JD**)  
Swisher International (**Christopher Casey, JD**)  
Cigar Rights of America (**Michael Copperman**)

1:30 PM     ***Little Cigars***

Cheyenne International (**Ralph Brown**)

1:45 PM     ***Pipe Tobacco***

Scandinavian Tobacco Group US (**Daniel McGee, JD**)  
Republic Tobacco (**Carl loos, MBA**)

2:05 PM     ***E-Cigs & Other Vapor Products***

SFATA (**Glenn Kassel**, Freedom Smokeless)  
ECIG (**Bryan Haynes, JD**, Troutman Sanders)  
AEMSA (**Lou Ritter**, AEMSA)

2:35 PM     **Open Discussion** with Attorney Panelists: Similarities and Differences in the  
Initial Impressions for Deeming Across Product Sectors

Attorney Panelists:   **Ben Haas, JD** (Latham & Watkins)  
                              **Marc Scheineson, JD** (Alston & Bird)  
                              **David Adams, JD** (Venable)  
                              **Azim Chowdhury, JD** (Keller & Heckman)  
                              **Phil Daman, JD** (Daman & Associates, LLP)

- 3:10 PM Coffee / Tea Break
- 3:25 PM **Substantial Equivalence Case Studies:** What Works?  
*Session Moderator: **Dean Cirotta, MBA** (EAS Consulting Group)*  
Republic Tobacco (**Carl loos, MBA**)  
Lorillard Tobacco (**Dr. Neil Wilcox, DVM, MPH**)  
Swedish Match (**Ben Haas, JD**, Latham & Watkins)
- 4:10 PM **Open Discussion** with Presenters and Attorney Panelists
- 4:45 PM Session Concludes
- 5:00 PM TMA Board Meeting **Fairfax Room**
- 7:00 PM Opening Reception **Moody's Tavern**
- 8:00 PM Dinner on Your Own



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#### Tuesday, May 20<sup>th</sup> - Evidence-Based Science and FDA Tobacco and E-Cig Regulation

9:00 AM Evidence-Based Science, Sufficient Evidence and Philosophy of Science

**Farrell Delman, MS, MA** (TMA)

9:15 AM The Current Political-Economy of Nicotine and Tobacco in the US and  
Around the World: Where We are Today

**Farrell Delman, MS, MA** (TMA)

**Darryl Jayson, MA** (TMA)

**Chris Moll, MS** (TMA)

9:45 AM A History of FDA Tobacco Regulation (Round-Table Discussion)

Moderator: **Jim Solyst, MS** (Swedish Match North America)

**Mitchell Zeller, JD**, Director, FDA -CTP

**Scott Ballin, JD** (Public Health Consultant)

**Steven Parrish, JD** (Steve Parrish Consulting Group)

11:00 AM Coffee/Tea Break

11:15 AM Tobacco Harm Reduction: Its Origins and Status

Presentation: **David Swenor, JD** (University of Ottawa)

Introduction: **Jim Solyst, MS** (Swedish Match North America)

11:35 AM Vapor: Disposables, Cartridges and Personal Vaporizers

Moderator: **Farrell Delman, MS, MA** (TMA)

Presentation: **Dr. Bill Bartkowski, PhD** (VapAria)

Panelists: **Linc Williams** (AEMSA)

**John Wiesehan Jr.** (Ballantyne Brands-Mistic)

**Spike Babaian, MA** (Vape New York)

12:30 PM Lunch

**Burwell Plantation Room**

1:00 PM Keynote Luncheon Speaker:

**Dr. Michael Thun, MD, MS** (formerly ACS): "A Cautionary Tale" (by video)

Introduction: **Farrell Delman, MS, MA** (TMA)

Afternoon Moderator: **Scott Leischow, PhD** (Mayo Clinic)  
Introduction: **Farrell Delman, MS, MA** (TMA)

- 1:45 PM Evidence-Based Regulation and Randomized Controlled Trials (RCT's)  
Electronic Cigarettes: What We Know Now & What We Need to Know  
Presentations:  
**Dr. Riccardo Polosa, MD, PhD** (University of Catania)  
**Dr. Konstantinos Farsalinos, MD** (Onassis Cardiac Surgery Center)  
**Dr. Christopher Bullen, PhD, MPH** (New Zealand NIHL) - by Skype
- 2:45 PM Coffee/Tea Break
- 3:00 PM A Strategic Agenda for E-Cig Research  
**Dr. David Abrams, PhD** (Schroeder Institute for Tobacco Research and Policy Studies at American Legacy Foundation)  
Evidence Needed to Inform Regulation including RCT's Needed to Address Individual & Population Risk  
Section 911 of the TCA  
How FDA Functions on MRTP Applications  
Hurdles for Key Products (E-Cigs and others)  
CTP vs. CDER on Regulatory Science: What Types of Data Count - EPI vs Clinical Trials vs. Constituent Analyses
- 3:40 PM CRO/Laboratory Expert Advisory Panel  
**Dr. Gene Gillman, PhD** (Enthalpy Analytical)  
**Dr. Don Graff, PhD** (Celerion)  
**Randy Courington** (Arista Laboratories)
- 3:45 PM Q&A Panel Discussion on Funding the Way Forward and the Viability of an E-Cig Regulatory Science Foundation with:  
**Drs. Polosa, Farsalinos, Bullen, and Abrams, Jan Andries Verleur** (VMR/V2); **John Wiesehan Jr.**, (Ballantyne Brands-Mistic); **David Graham** (NJOY); **Miguel Martin** (LOGIC); **Charles Hamshaw-Thomas** (E-Lites)
- 5:00 PM Session Concludes
- 6:00 PM Welcome Reception: Cocktail Party and Barbeque **River Pool Complex**
- 9:00 PM Conclusion



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### Wednesday, May 21<sup>st</sup> - The Nicotine Industry Today

9:00 AM In Memoriam: Bill Greiwe (**Ralph Brown**, Cheyenne International)

*Morning Moderator: **Darryl Jayson, MA** (TMA)*

9:30 AM Supply and Demand of Nicotine from Source to Consumer  
Presentations:

Nicotine Extracts and E-Cigarettes (**Laurent Leduc**, E-Cig Consultant)

Sales Trends - Nicotine Products Retail Variety and Distribution  
(**Don Burke, MBA**, Management Science Associates, Inc.)

10:20 AM Panel Discussion: The Evolving Nicotine Consumer

Panelists: **Larry Wexler** (National Tobacco Co.)

**Dr. Gil Ross, MD** (American Council on Science and Health)

**George Cassels-Smith** (Tobacco Technology, Inc.)

**Eduardo Berea, MS** (Mother Murphy's)

**Dr. Michael Hufford, MD, PhD** (e-Nicotine Technology)

11:00 AM Coffee / Tea Break

11:15 AM Wall Street's View of the Tobacco and Nicotine Industries

Panelists:

**Erik Bloomquist, MBA** (Berenberg Bank)

**Ann Gurkin, MBA** (Davenport Inc.)

**Judy Hong, MBA** (Goldman Sachs)

**Bonnie Herzog, MBA** (Wells Fargo)

12:30 PM Lunch: TMA Annual Meeting

**Burwell Plantation Room**

Minutes, Election of Directors, President's Address

100th Anniversary Survey Distribution and Collection

Chairman's Presentation

**Marvin Coghill Lifetime Achievement Award (Alliance One)**

- 2:00 PM Global Regulatory Restraints  
Moderator: **Jim Solyst, MS** (Swedish Match North America)  
Presentations:  
**Dr. Alan Hardacre, PhD** (Imperial Tobacco Group) - The EU Tobacco Products Directive  
**Dr. Steve Stotesbury, PhD** (Imperial Tobacco Group) - The Impact of Public Policy Restrictions on Smoking Prevalence
- 3:00 PM Coffee / Tea Break  
Panelists:  
**Scott Leischow, PhD** (Mayo Clinic)  
**Nancyellen Keane, JD** (Troutman Sanders)  
**Charles Hamshaw-Thomas** (E-Lites)  
Topics to Include:  
Taxation/Prices; E-Cigs as Tobacco Products or Not: Restrictions on Sales and Use  
De-Normalization of Smoking  
Policies to Affect Attractiveness  
Graphic and Plain Packaging  
Flavorings and other Product Standards Including Nicotine Reduction  
Marketing: Point of Sale Advertising and Licensing Restrictions  
Leaf Sustainability
- 5:00 PM Session Concludes
- 7:00 PM Evening Cocktail Party and Sit-Down Dinner **James River Ballroom**  
Host: **Rob Wilkey, JD, MPH** (TMA Chairman)  
**“Giant of the Industry” Award to Joel Sherman** (Nat Sherman, Inc.)  
Presented by **Bill Sherman**
- 10:00 PM Conclusion



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#### Thursday, May 22<sup>nd</sup> - Nicotine Delivery and the Mission of Tobacco Control

9:00 AM E-Cig Safety, Nicotine Addiction and Smoking Cessation

*Morning Moderator: Dr. Joel Nitzkin, PhD (R Street, Formerly American Association of Public Health Physicians Tobacco Task Force)*

Presentations:

**Dr. K. Michael Cummings, PhD, MPH** (Medical University of S. C.)  
by video

**Dr. Michael Siegel, MD, MPH** (Boston Univ. School of Public Health)  
**Dr. Scott Leischow, PhD** (Mayo Clinic)

Topics to Include:

Nicotine's Health Effects

Nicotine in NRT Products, E-Cigs and Other Tobacco Products

Is Nicotine Addiction a Disease?

Behavioral vs. Nicotine, Flavor and Other Satisfaction from E-Cigs

Reduced Nicotine Cigarettes

The Massachusetts Nicotine Study: Cigarette Trends

10:30 AM Discussion Amongst Presenters

11:00 AM Coffee / Tea Break

11:15 AM Discussion with Panelists:

**Dr. Gil Ross, MD** (American Council on Science and Health)

**David Graham, MPPA** (NJOY)

**Miguel Martin** (LOGIC)

**Dr. Riccardo Polosa, MD, PhD** (University of Catania)

**Dr. Konstantinos Farsalinos, MD** (Onassis Cardiac Surgery Center)

**Dr. Jonathan Foulds, PhD** (Penn State College of Medicine)

**Dr. Michael Moynihan, PhD, MS** (22nd Century Group)

12:00 PM Lunch

**James River Prefunction C & D**

1:00 PM Tobacco Control's Mission in 2014 and for the Next 50 Years

Afternoon Moderator: **David Sweanor, JD** (University of Ottawa)

Video: "Blowing Smoke" **Dr. Alan Blum, MD** (University of Alabama) by Skype

Presentations:

Deeming's Impact on the States and Localities

**Jeff Stier, JD** (National Center for Public Policy Research)

Taxation and Other Effective Control Policies

**Dr. K. Michael Cummings, PhD, MPH** (Medical University of S.C.)

US Smoking Prevalence Rates, E-Cigs and Healthy People 2020

**Chris Moll, MS** (TMA)

The PATH Study

**Dr. Corinne Husten, MD** (FDA - Center for Tobacco Products)

The ISCD Expert Panel on the Risk Continuum

**Dr. Jonathan Foulds, PhD** (Penn State, College of Medicine)

2:30 PM Coffee/Tea Break

2:45 PM Panel Discussion

Topics to Include:

Public Health Efforts Proportionate to the Continuum of Risk

Distinguishing Cigarettes from Tobacco

Smoking Cessation: What Works?

NRT vs. Lifestyle Nicotine Delivery (including E-Cigs and Snus)

Does Nicotine Pleasure/Addiction Have a Place and if so Where?

Tobacco Control Restrictions: What Works?

Differential Taxation Based on a Continuum of Risk?

De-Normalization vs. Re-Normalization: the Population Risk Issue

Inspiring More Cigarette Quit Attempts Regardless of the Method Used; 480,000 Deaths: Is Doing Nothing Feasible?

Invited Discussants for this Final Session include all Conference Presenters and Panelists above who identify themselves as members of the public health community as well as other members of the public health community who are attending the conference and wish to share their thoughts.

4:00 PM Conference Concludes