enicotine TECHNOLOGY

Taking the Smoke Out of Smoking

Jeffrey Williams
Co-Founder & CEO
e-Nicotine Technology, Inc.
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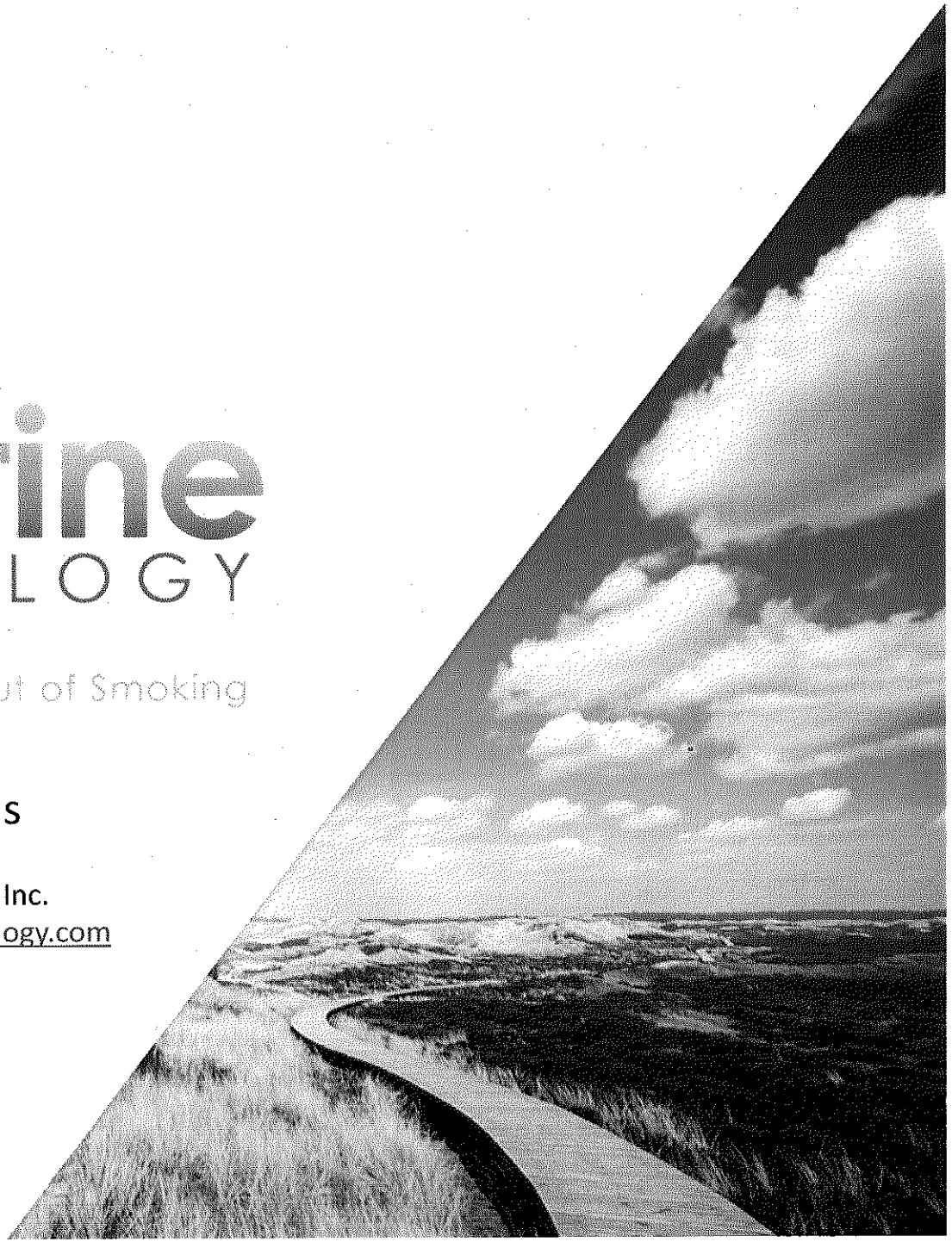
+925.876.2765



OMB Meeting – 18 Dec2013

Key Points

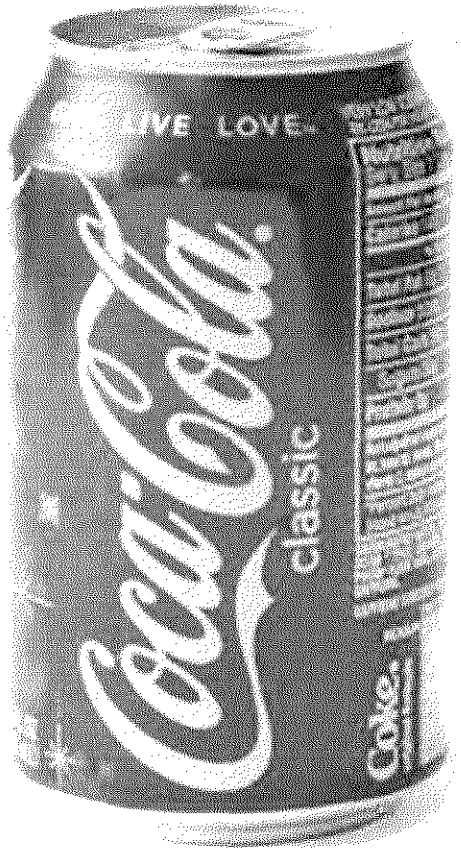
1. **e-Nicotine Technology (eNT) is a science-based company founded by pharmaceutical industry executives with no ties to the tobacco industry**
2. Our innovative technology can reduce smoking urges almost immediately, while delivering a fraction of the nicotine of a cigarette and none of the carcinogens
3. eNT has met with the CTP, and they agree with our development plan
4. However, forcing products like ours down a PMTA or MRTP pathway will push innovations like ours – including the job creation, taxation, and public health benefits – overseas

Our Mission

eNT is a healthcare company committed to reducing the harm associated with tobacco products by delivering nicotine aerosols with carefully controlled particle sizes to enable deep lung delivery and thus rapid nicotine delivery, helping individuals transition from smoking

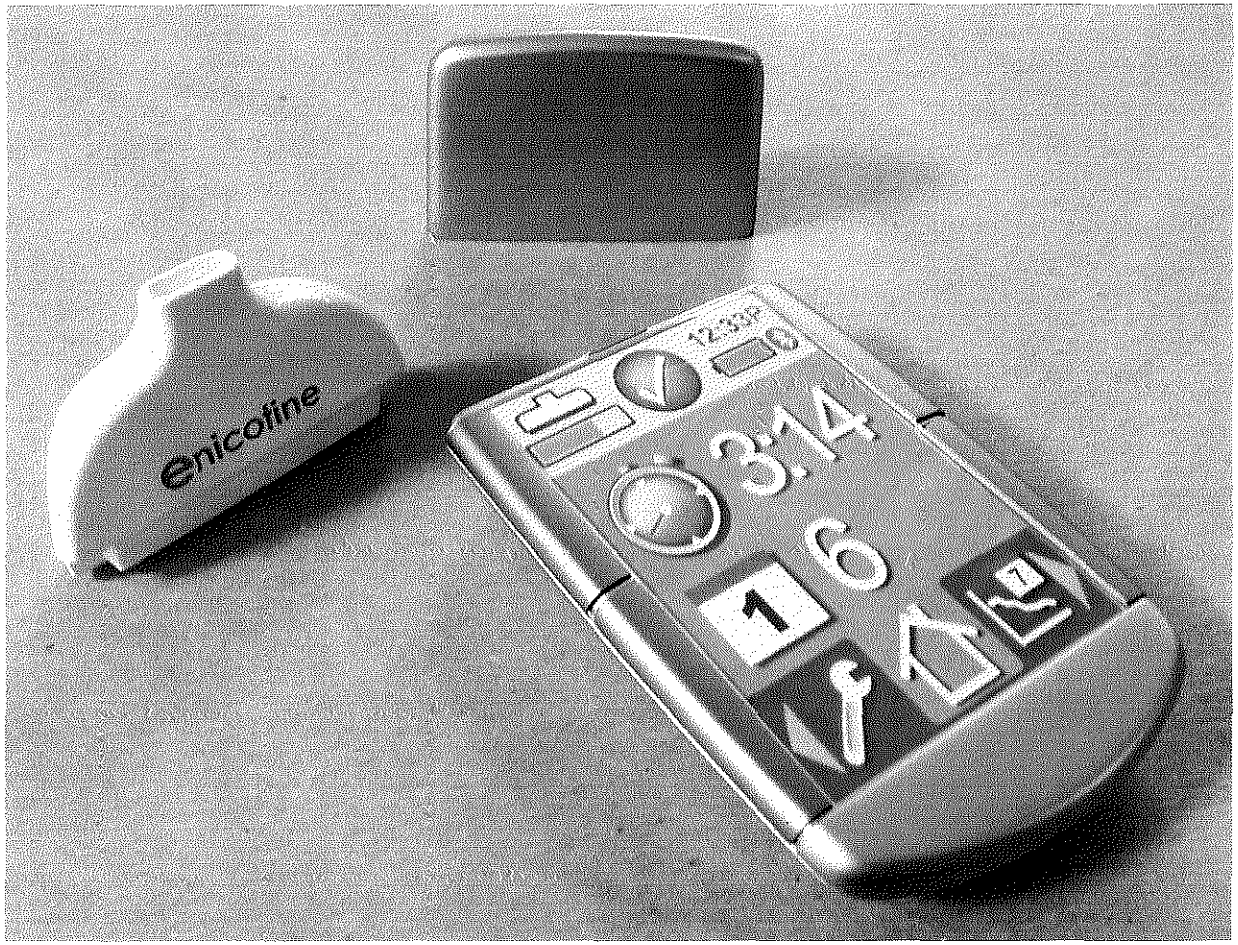
We are changing nicotine delivery from this…

To Be More Like This…



Using Our Innovative Nicotine Delivery Technology

- ✓ Reusable controller
- ✓ Consumable dose cartridge (with 500-1000 inhalations)
- ✓ Deep lung delivery of nicotine
- ✓ Proprietary eHealth tools to help smokers reach their goals



Pharmaceutical Experienced Management Team

Personnel	Yrs Exp	Role	History
Jeffrey Williams	25	CEO	• Started several drug delivery and medical device companies • Raised over $500M in private and public capital • Recruiting and building organizations to successful exits
Michael Hufford, PhD	20	CMO	• Nicotine and smoking cessation expert • FDA-approval (Savella®, milnacipran), more than 100 publications & patents • 19 years experience in application development for mobile computing
Martin Wensley	25	CTO	• 8 devices moved into clinic or commercialized • Experienced developing products under FDA and other federal regulatory agencies (e.g., FAA) • 47 issued patents

Experienced Commercial Product
Experienced BOD / Investors

- Don Watkins (Chair)
- Rich Brenner
- Fraser Bullock
- Chris Munday
- Jeff Williams
- Michael Hufford, PhD

the brenner banner

SORENSON CAPITAL

NTAN North Texas Angel Network
We Invest In People!

BainCapital

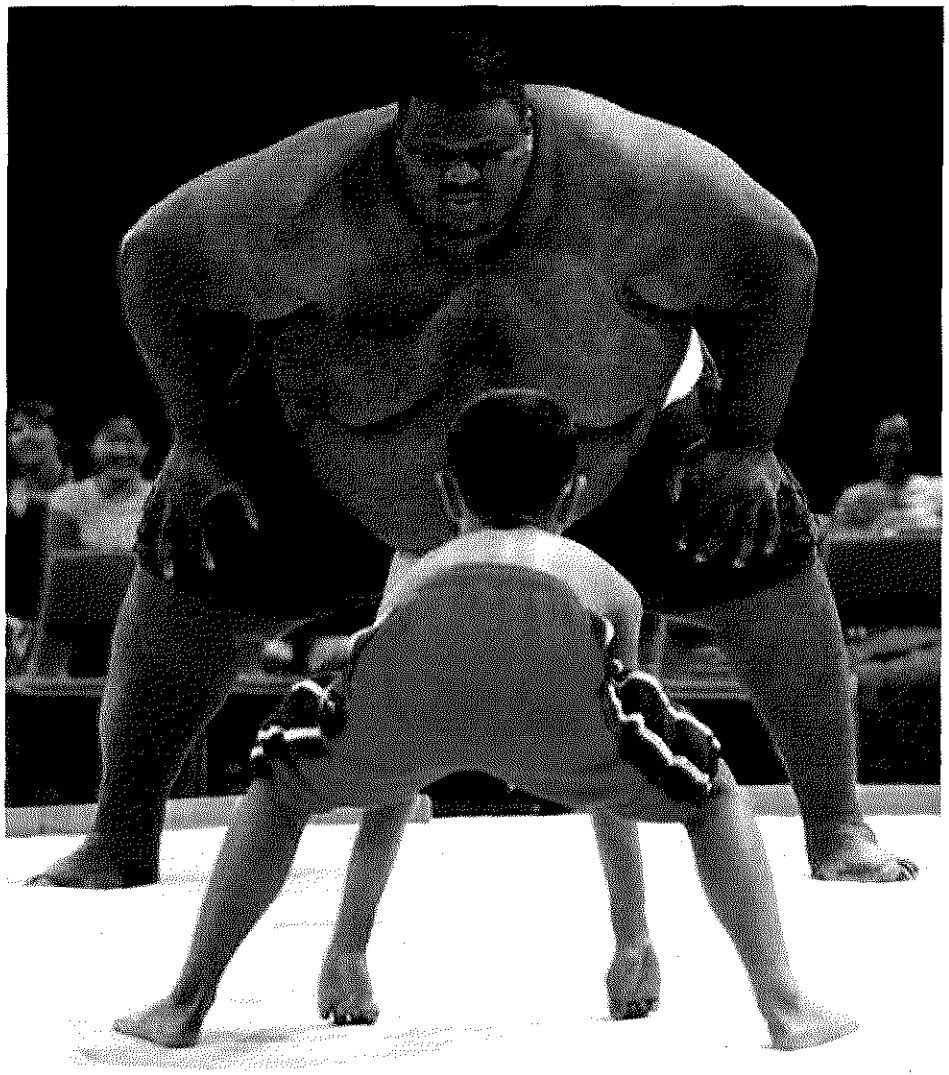
Skullcandy

HandStands

GOLDEN GATE CAPITAL

LIFE SCIENCE ANGELS
Investing For Life

We Have our Work Cut Out for Us vs. Big Tobacco



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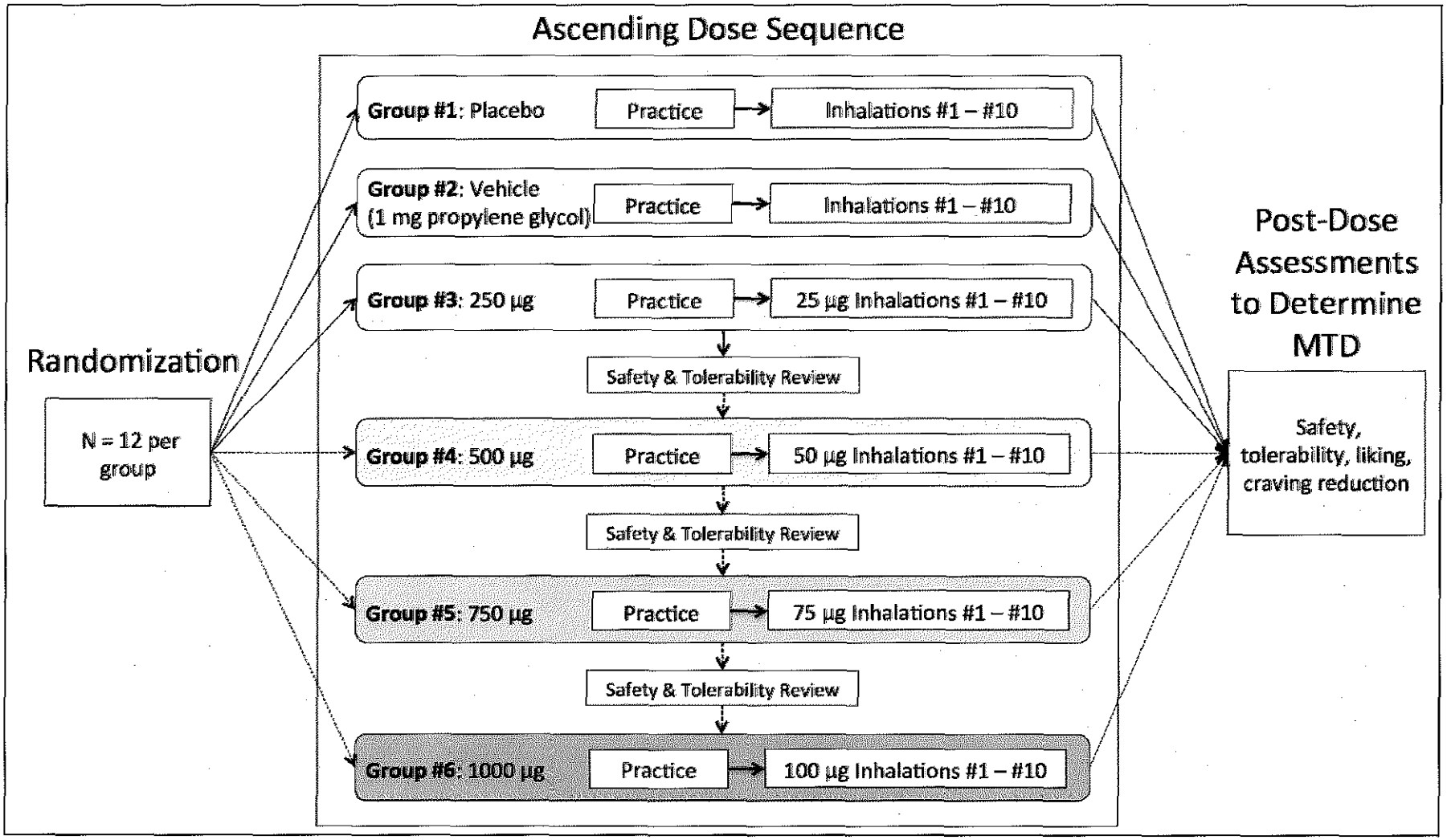
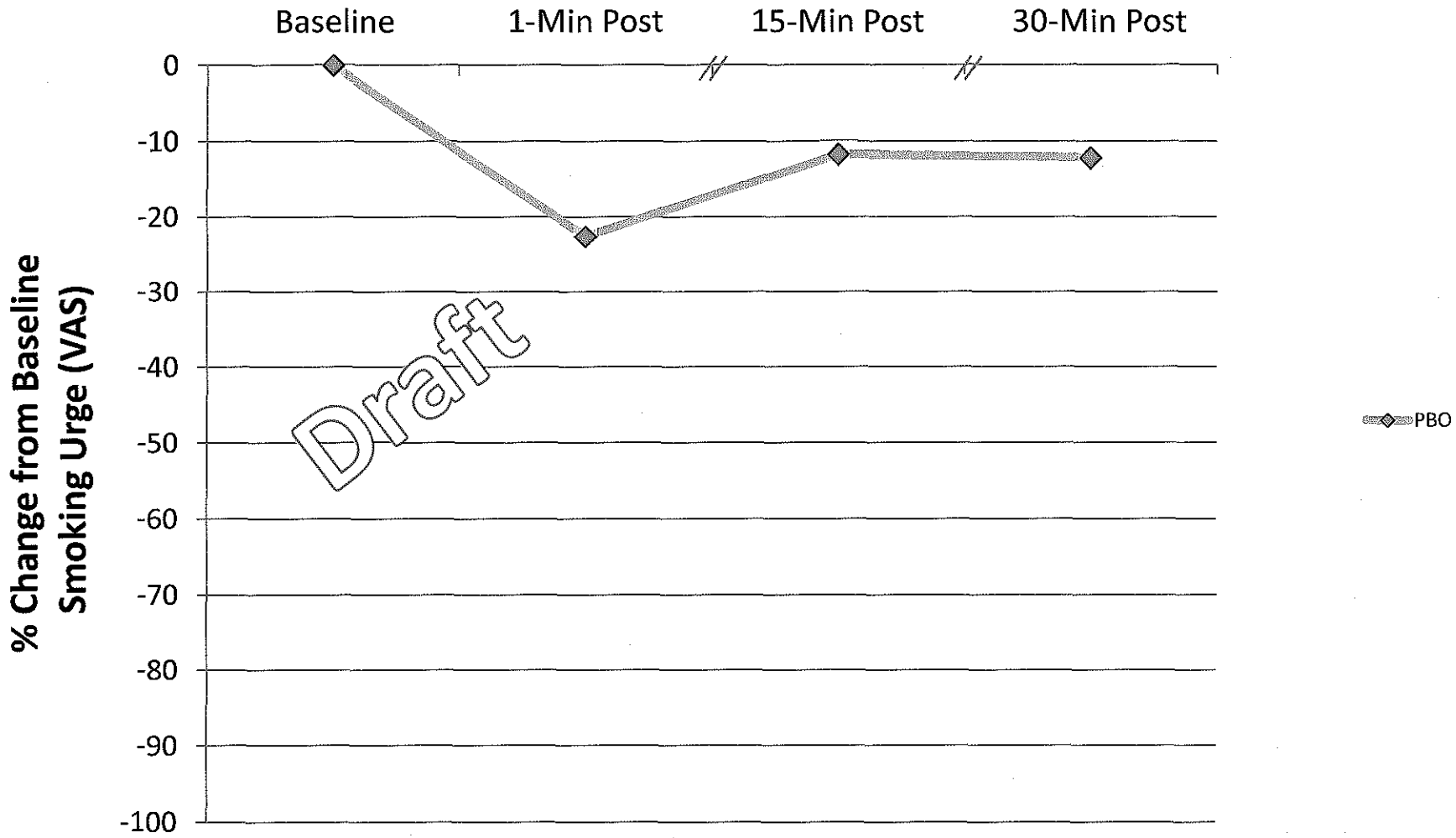
Data Driven: eNT-101 Clinical Trial



Smoking Urge:
% Change from Baseline



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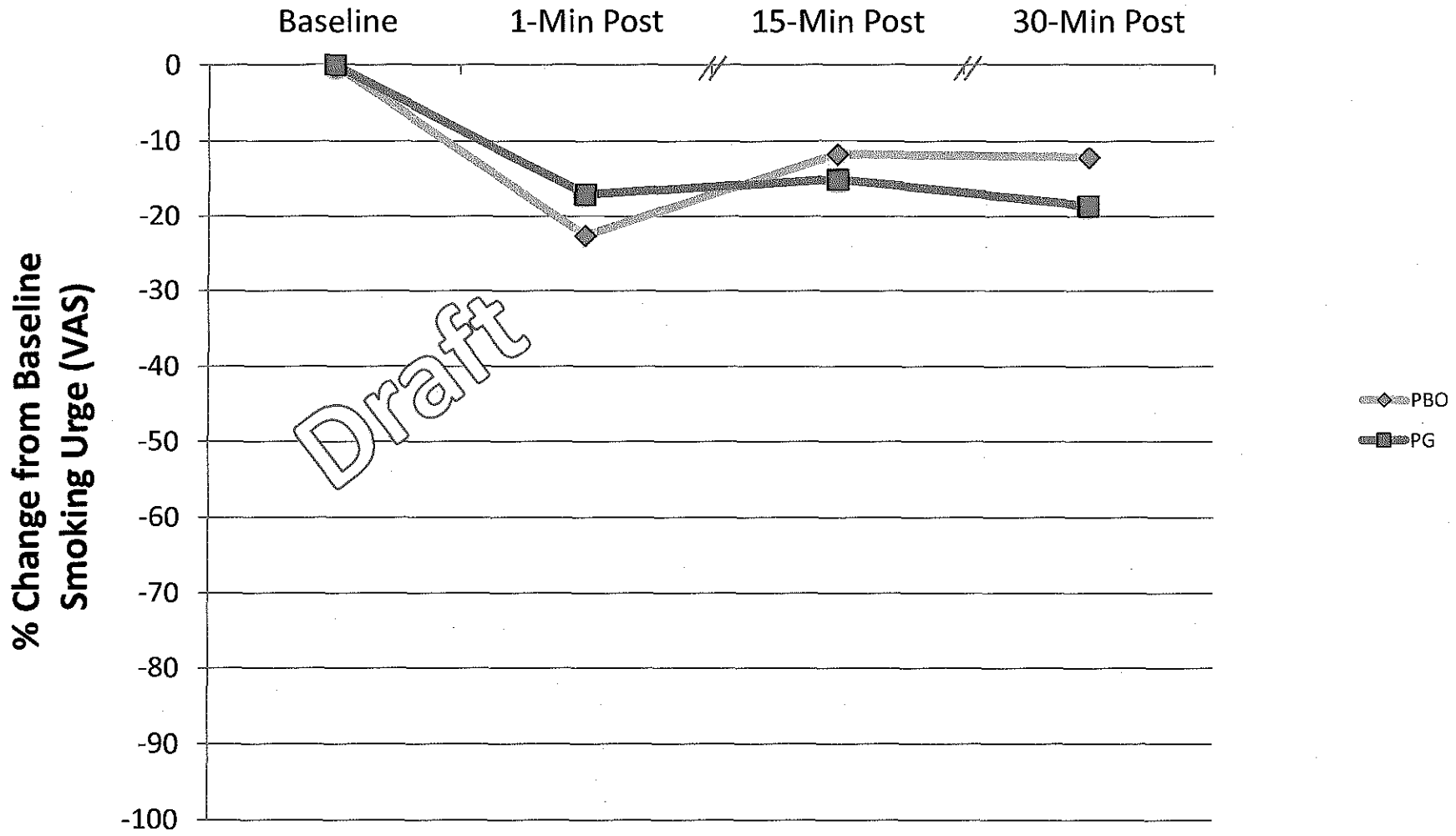

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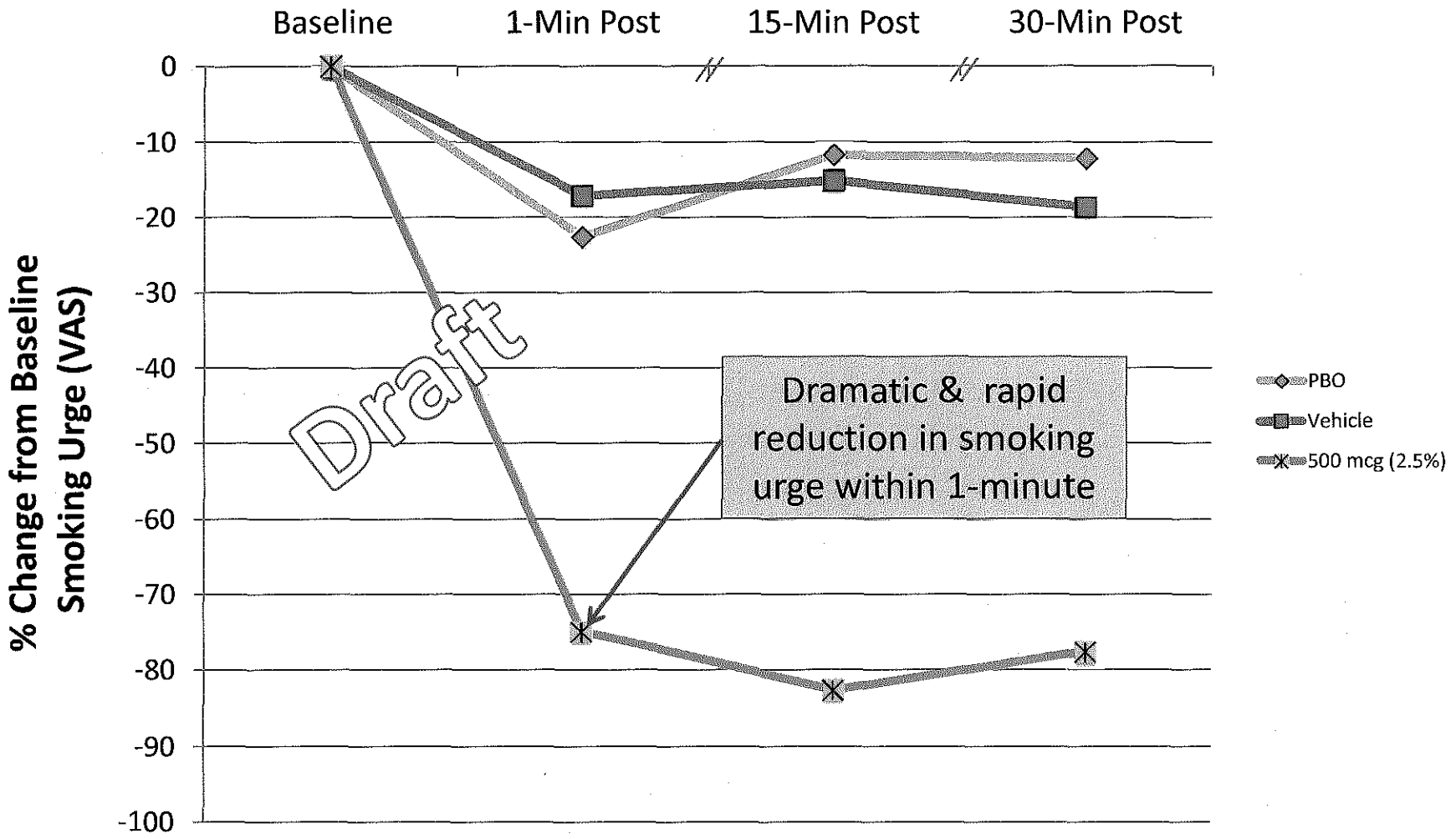
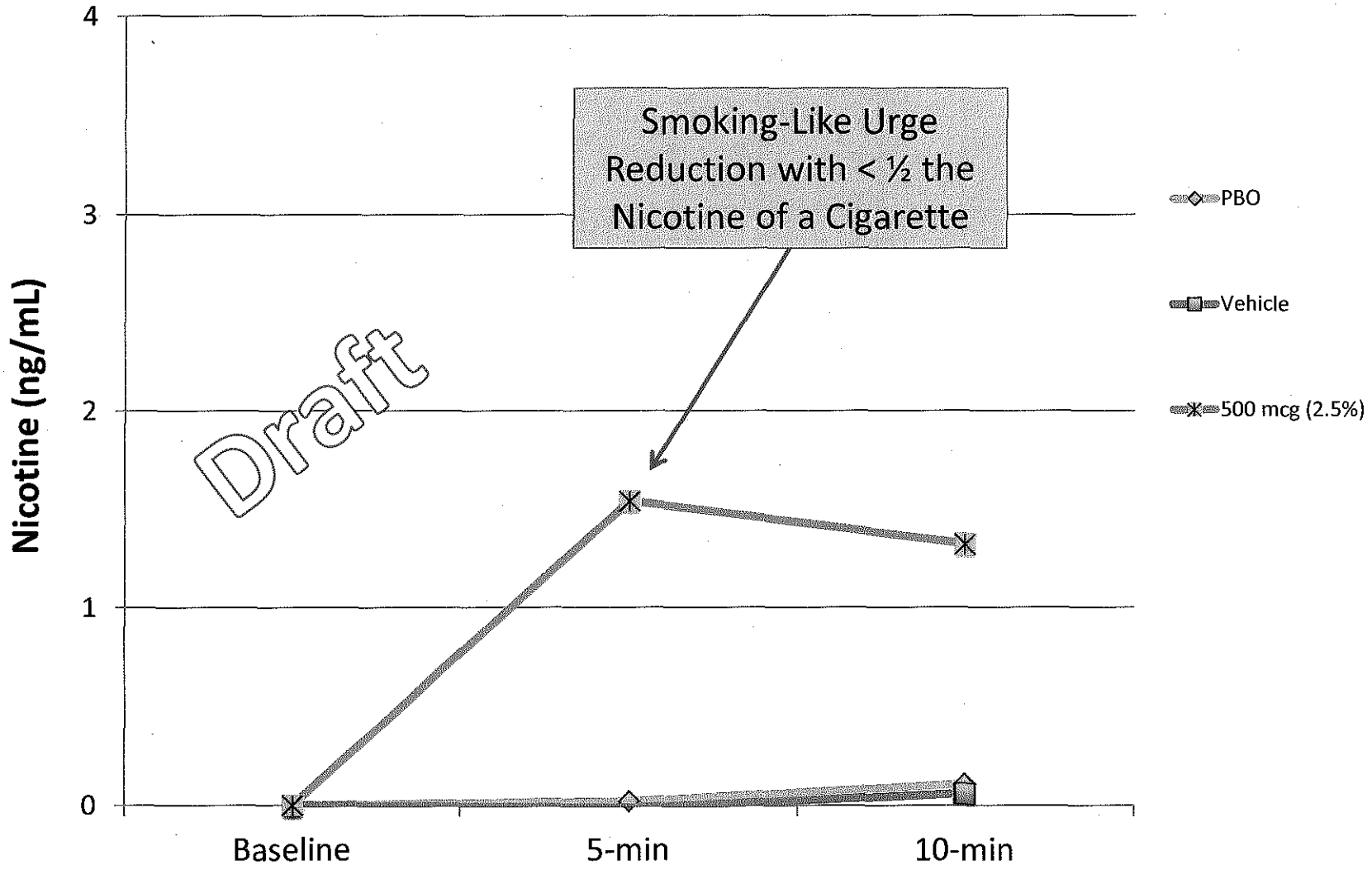


Blood Nicotine Levels



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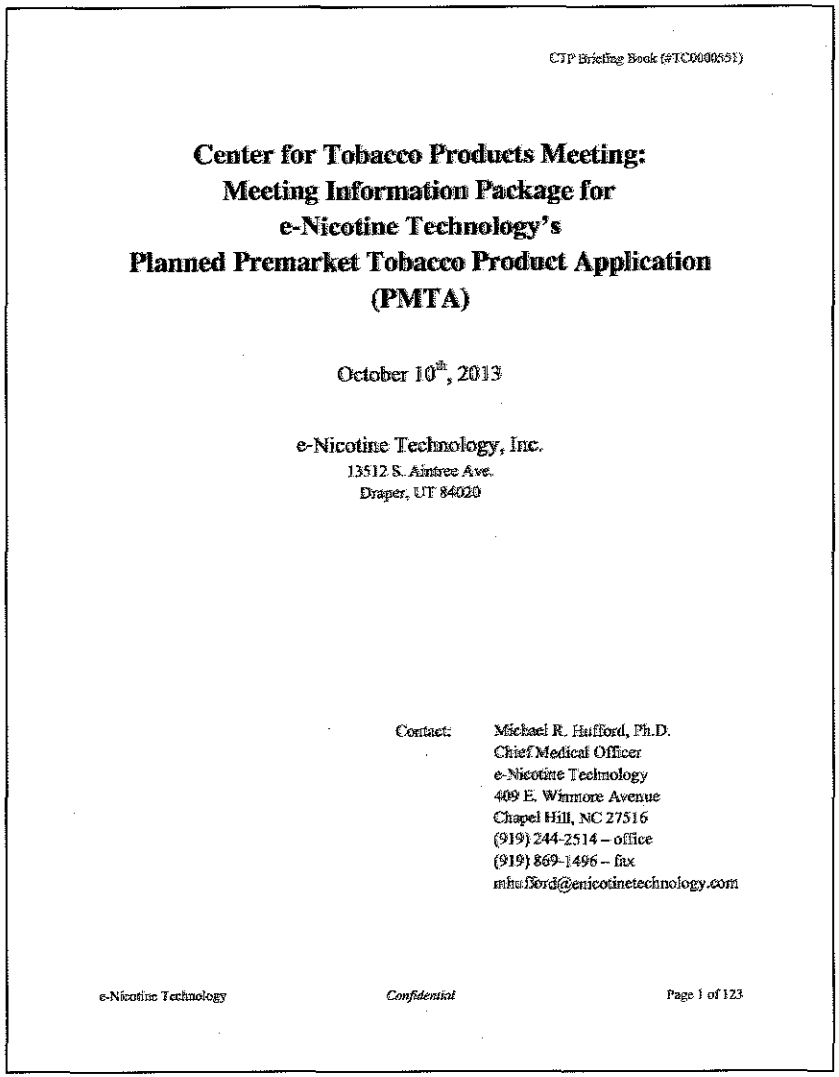
FDA Meeting Details

- Date: October 10th, 2013
- Location: CTP headquarters (Rockville, MD)
- Attendees: eNT – Hufford, Wensley and Williams
  CTP – 20+ attendees
- Context: PMTA meeting (pre-market new tobacco product)
- Timeline:
  - Original meeting request submitted: 5-Dec-2012
  - Follow-on request submitted: 21-Jun-2013
  - Meeting granted: 26-Jul-2013
  - Briefing book submitted: 22-Aug-2013
  - Meeting held: October 10-Oct-2013

Prepared Detailed: FDA Briefing Book

- 120+ pages, including:
  - Product rationale
  - Safety and toxicity of nicotine and propylene glycol
  - Nonclinical development plan
  - Clinical development plan
  - Abuse liability assessment plan
  - Quality system
  - Commercial device development
  - Risk mitigation strategy



CTP Briefing Book (#TC0000551)

Center for Tobacco Products Meeting:
Meeting Information Package for
e-Nicotine Technology's
Planned Premarket Tobacco Product Application
(PMTA)

October 10th, 2013

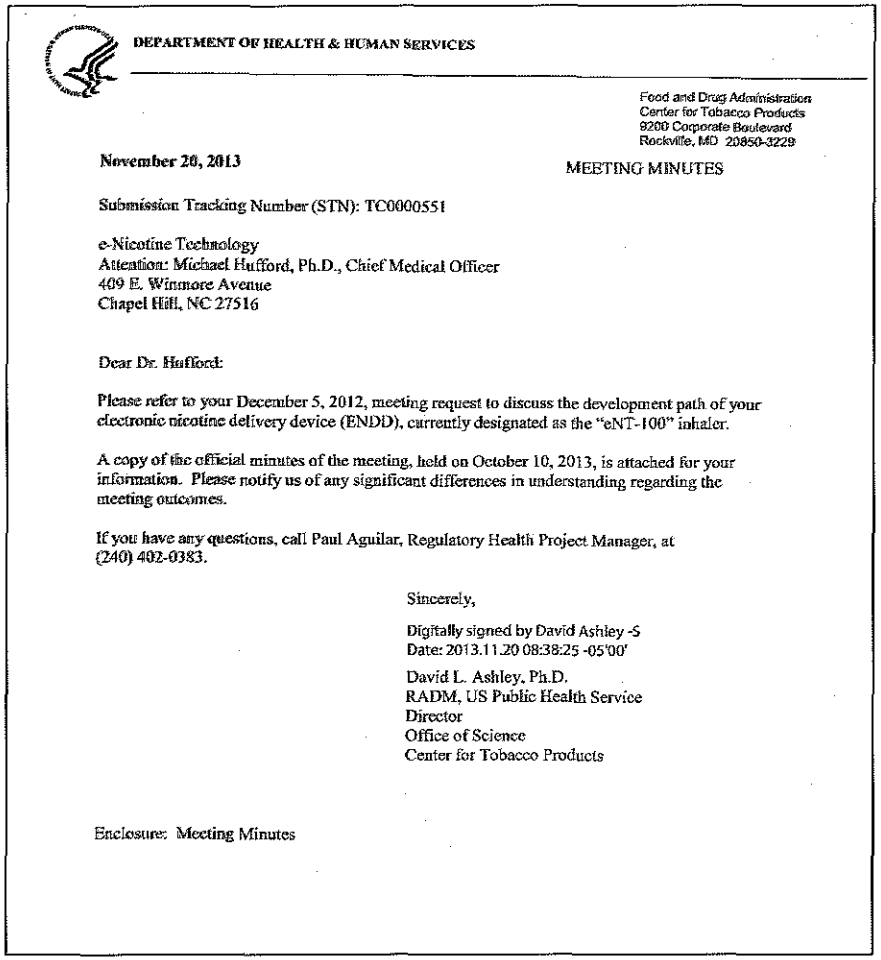
e-Nicotine Technology, Inc.
13512 S. Aintree Ave.
Draper, UT 84020

Contact: Michael R. Hufford, Ph.D.
Chief Medical Officer
e-Nicotine Technology
409 E. Winmore Avenue
Chapel Hill, NC 27516
(919) 244-2514 – office
(919) 869-1496 – fax
mhufford@enicotinetechnology.com

e-Nicotine Technology *Confidential* Page 1 of 123

CTP Agreed with our Development Plan for Approval as a PMTA

- CTP provided very helpful input on our development plan, and *"the research plan outlined in the application appears reasonable…"*



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville, MD 20850-3229

November 20, 2013

MEETING MINUTES

Submission Tracking Number (STN): TC0000551

e-Nicotine Technology
Attention: Michael Hufford, Ph.D., Chief Medical Officer
409 E. Winmore Avenue
Chapel Hill, NC 27516

Dear Dr. Hufford:

Please refer to your December 5, 2012, meeting request to discuss the development path of your electronic nicotine delivery device (ENDD), currently designated as the "eNT-100" inhaler.

A copy of the official minutes of the meeting, held on October 10, 2013, is attached for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes.

If you have any questions, call Paul Aguilar, Regulatory Health Project Manager, at (240) 402-0383.

Sincerely,

Digitally signed by David Ashley -S
Date: 2013.11.20 08:38:25 -05'00'

David L. Ashley, Ph.D.
RADM, US Public Health Service
Director
Office of Science
Center for Tobacco Products

Enclosure: Meeting Minutes

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FDA (US) vs. MHRA (UK): *Overview*

	U.S.	U.K.
Population (MM)	314	63
% smokers (market size)	19% (47MM smokers)	20% (10MM smokers)
Regular e-cig users (MM)	~6% (2.8M)	~7% (700K)
General regulatory attitude toward e-cigs	E-cigs may be harmful, they may act as a gateway to smoking among children, they must be proven to be safe and effective, smokers should quit completely	E-cigs are much safer then smoking, most of their use is by smokers to help them quit, they need to be regulated but nicotine is not bad for you

FDA (U.S.) vs. MHRA (U.K.): *Specifics*

	US: PMTA pathway through CTP	UK: Medicinal product through MHRA
Number of studies required to approval	10+	1-2
Type of studies	Clinical, nonclinical, abuse liability, health outcomes	PK and aerosol analysis
Clinical & Nonclinical development costs	~$14MM	~$3MM
Eventual marketing claim	None	NRT for smoking cessation
Manufacturing requirements	GMP with inspection	GMP with inspection
Fees for review	$0	$46K
Time for regulatory review	365 days	100 days

FDA (U.S.) vs. MHRA (U.K.): FDA longer and more costly

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We Do Believe ENDDs Should be Sensibly Regulated

- Electronic Nicotine Delivery Devices (ENDDs) should receive an *appropriately abbreviated and expedited review* if they are shown to deliver far fewer harmful or potentially harmful constituents as compared to conventional cigarettes
- Excessive regulation will prevent innovations in nicotine delivery to helping the US public, and push jobs and taxable revenues overseas

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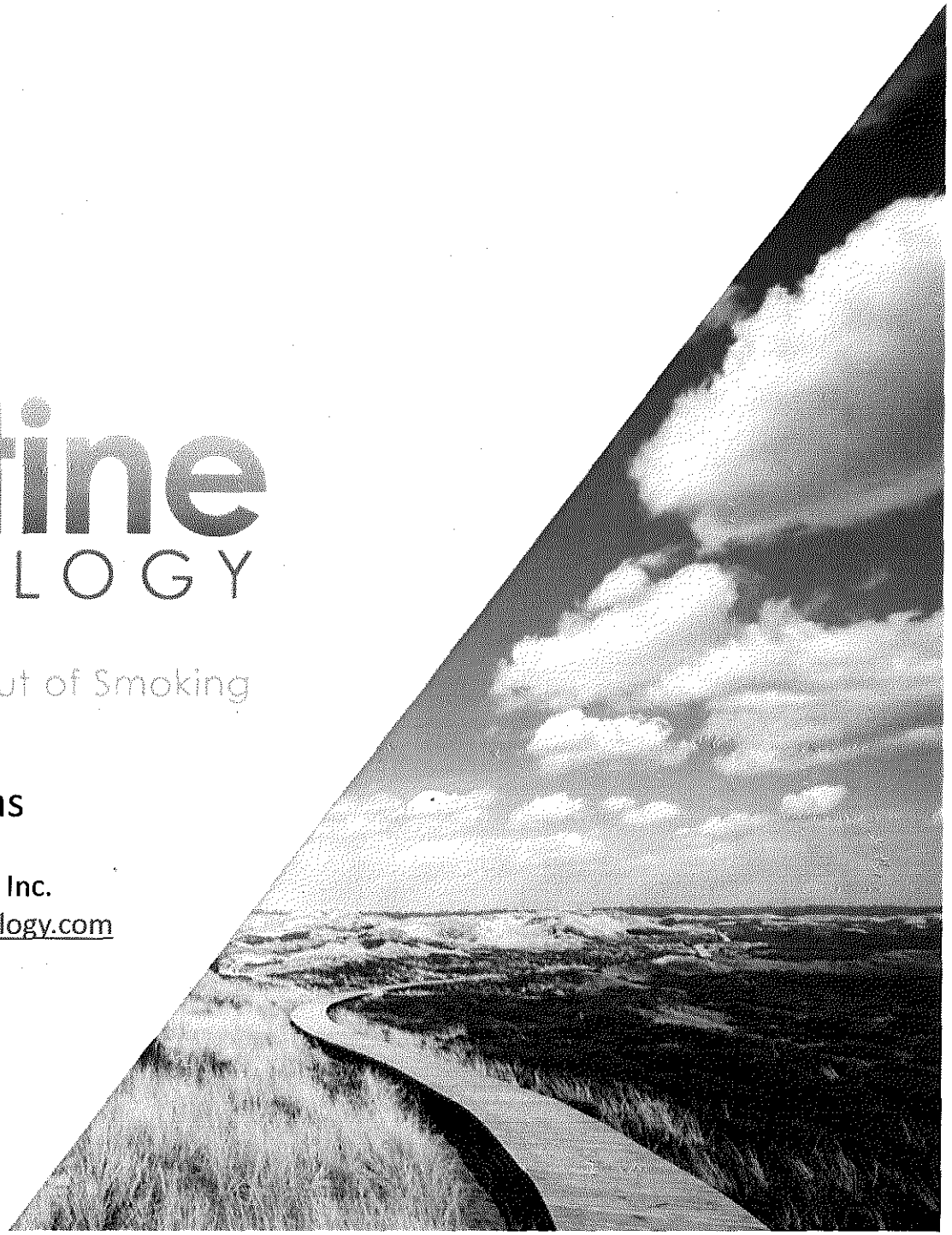

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