



# Michael Hufford, PhD

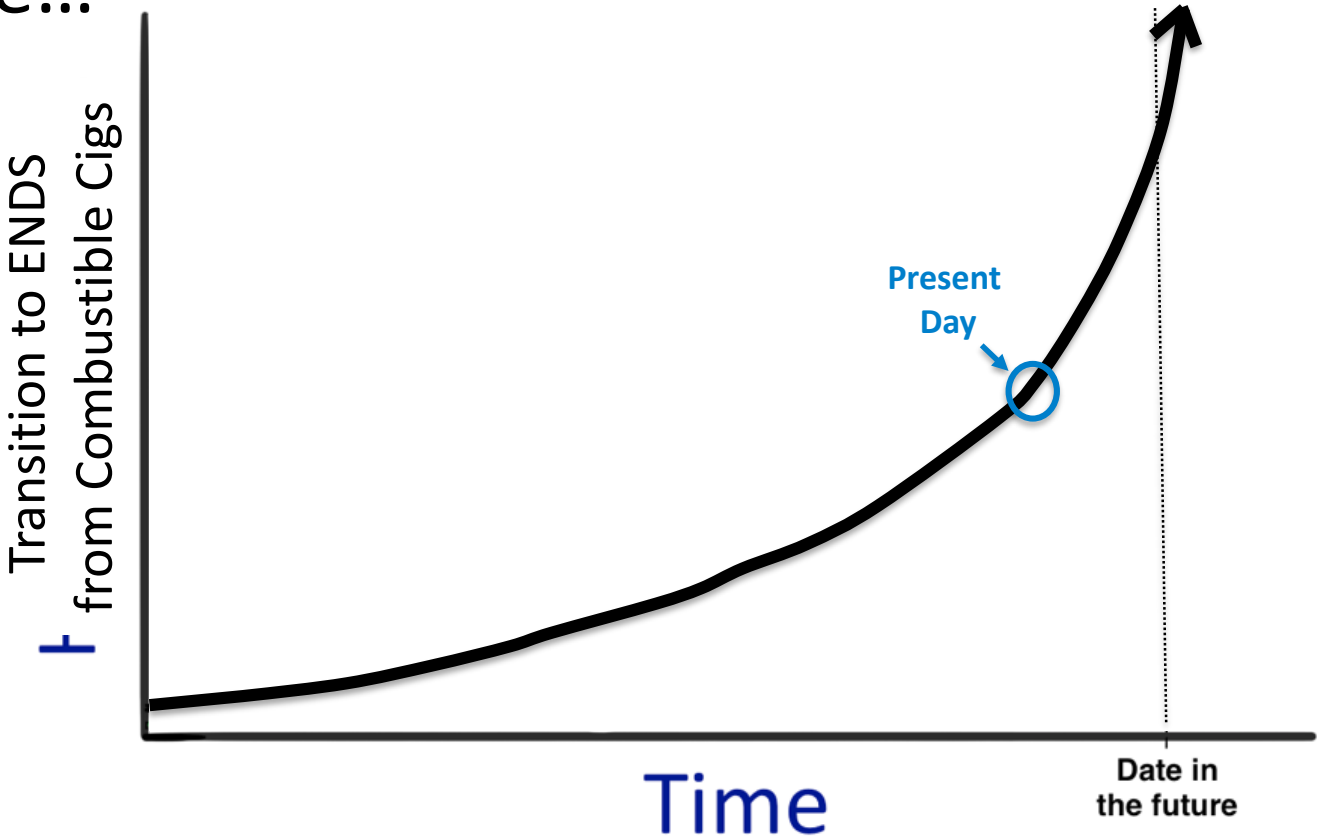
PinneyAssociates



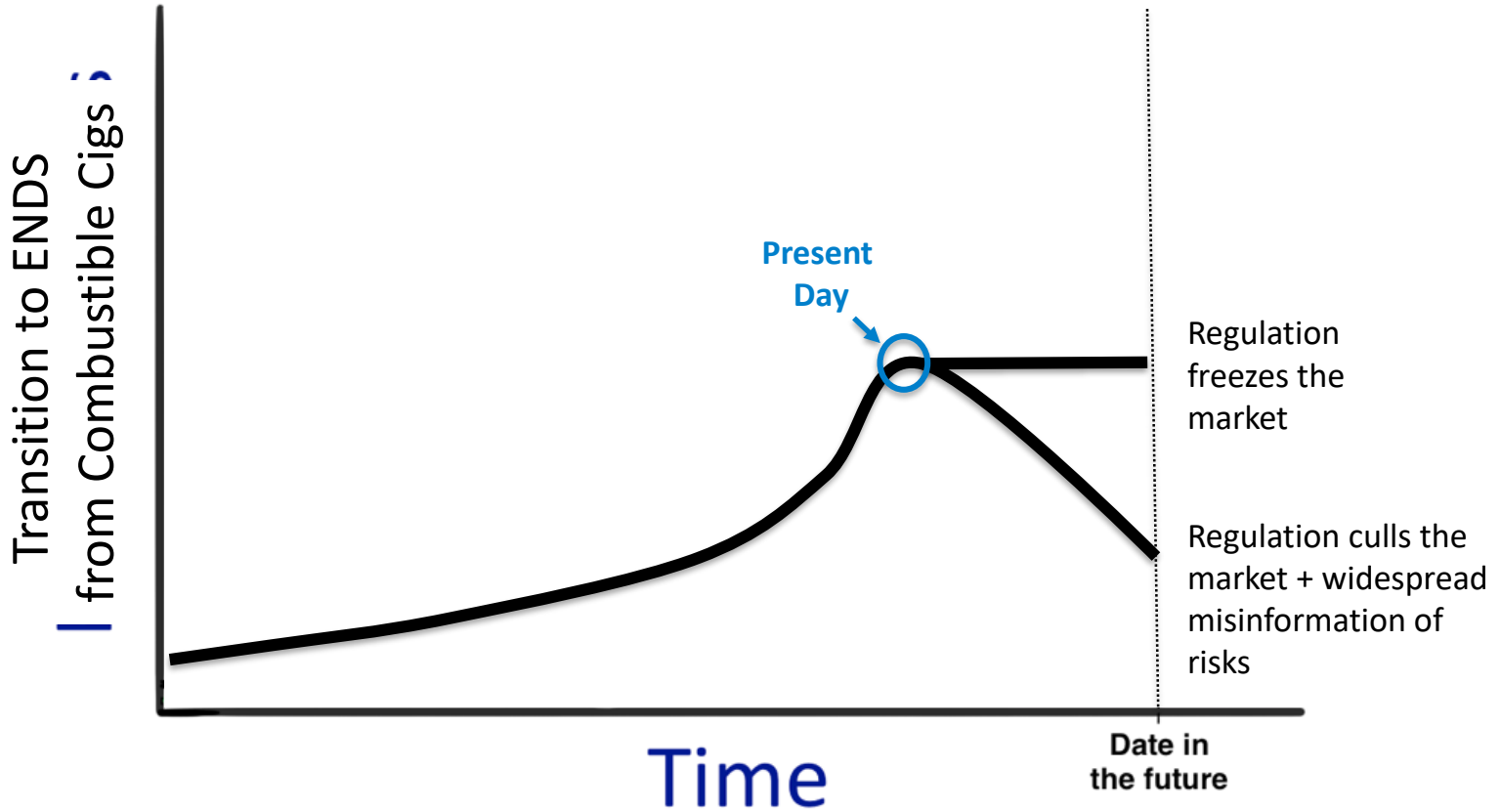
# Disclosures

- In the past three years **Pinney** Associates has provided services for a range of companies, including for NJOY, Inc., a developer and marketer of electronic nicotine delivery systems, and since February 2015, for Reynolds American, Inc. (RAI) on tobacco harm minimization
- Our work for RAI focuses on products, regulations, and policies related to smoking cessation and harm minimization; we do not work on combustible conventional cigarettes
- Financial support was provided by RAI for this presentation, but they had no input into any facet of this work

# My hope...



# My fear...





- Any tobacco product (other than those exclusively in test markets) on the market as of Feb. 15, 2007 is considered "grandfathered." Otherwise, any products that are introduced or modified on or after that date are considered "new" tobacco products and must submit a premarket application to the FDA through one of the three available pathways.

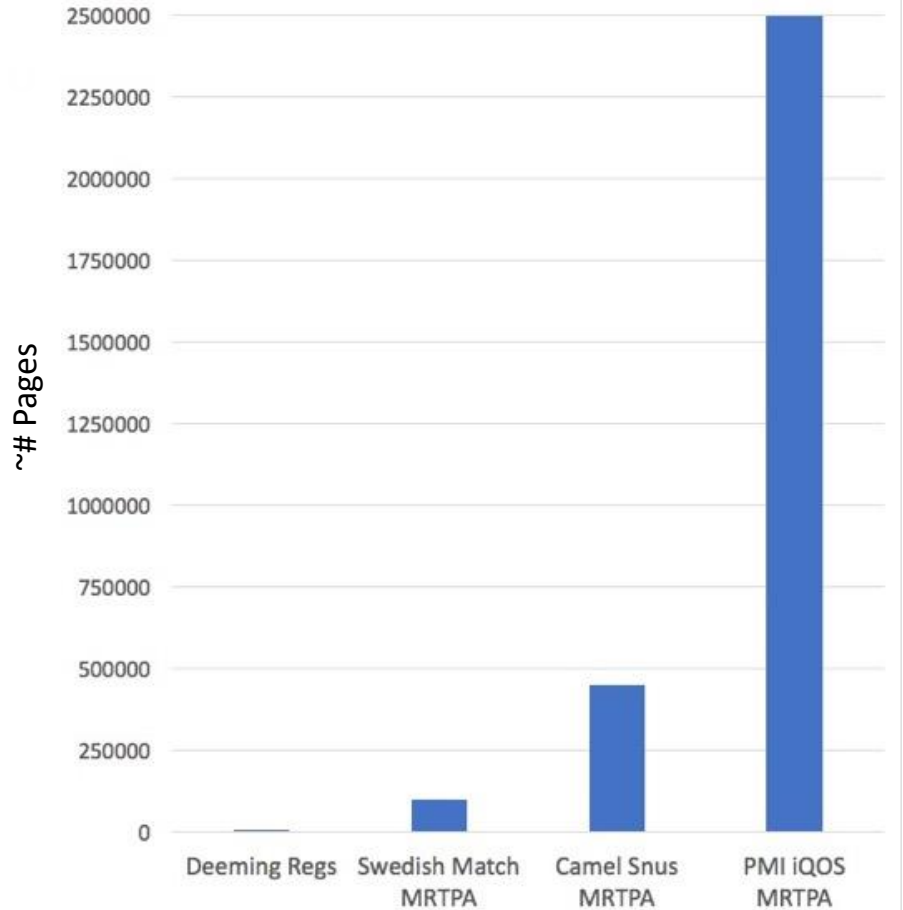
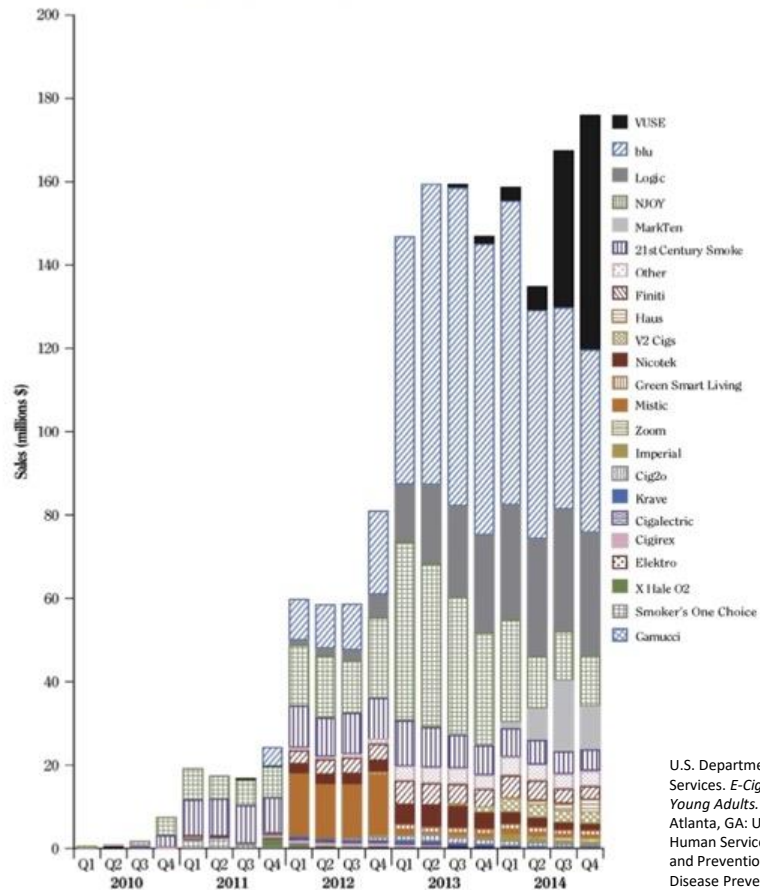


Figure 4.1 E-cigarette sales in tracked channels by brand, 2010–2014



U.S. Department of Health and Human Services. *E-Cigarette Use Among Youth and Young Adults. A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2016.

Source: Huang and Chaloupka (in press).  
 Note: Data points for this figure are shown in Table A4.1.1 in Appendix A.4.

“...in most revolutions,  
 it's the revolutionaries  
 who die first.”  
 – T. Goetz, 2017

## Big Tobacco



PHILIP MORRIS  
INTERNATIONAL



BRITISH AMERICAN  
TOBACCO



JTi

## Big Pharma

Johnson & Johnson



NOVARTIS

Pfizer



## Big Tech

Microsoft

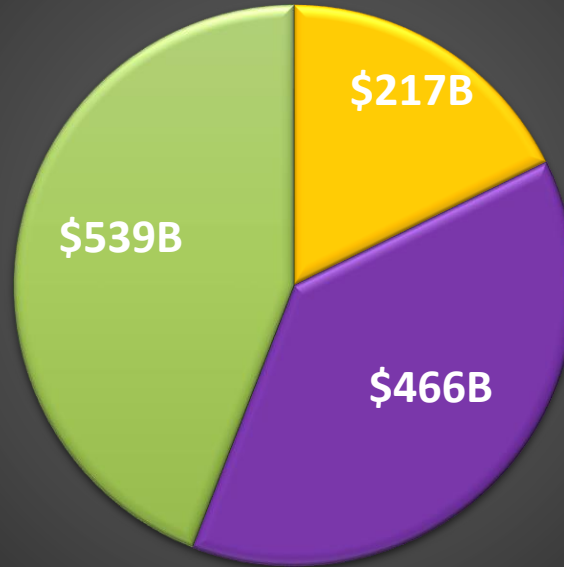


amazon

Google



# Total EBITDA Revenues (2009-2014)

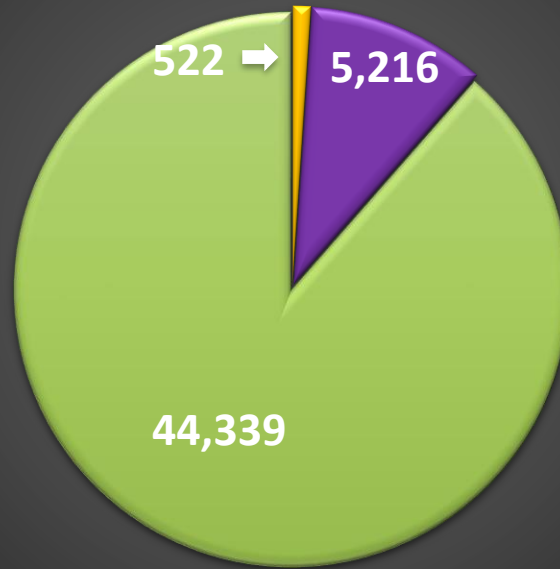


■ Tobacco   ■ Pharma   ■ Tech

\* EBITDA: Earnings before interest, tax, depreciation and amortization, a measure of a company's operating performance



## Cumulative US Patent Applications (2009-2014)



■ Tobacco   ■ Pharma   ■ Tech

