

E-REGISTRY BILLS AND THEIR IMPLICATIONS FOR PUBLIC HEALTH



PUBLIC HEALTH
LAW CENTER
at Mitchell Hamline School of Law

TODAY'S PANELISTS

Presenters:

- Megan Boelter, Western Regional Director, Preventing Tobacco Addiction Foundation/ Tobacco 21
- Ashley Lyerly, Senior Director of Advocacy, American Lung Association
- Claudia Rodas, Regional Advocacy Director, Southern Region, Campaign for Tobacco-Free Kids
- Janine Young, Senior Health Inspector, San Francisco Department of Public Health







Moderators:

- Tom Pryor, Public Health Law Center
- Marisa Katz, Public Health Law Center

THE PUBLIC HEALTH LAW CENTER



LEGAL TECHNICAL ASSISTANCE

-  Legal Research
-  Policy Development, Implementation, Defense
-  Publications
-  Trainings
-  Direct Representation
-  Lobby



based on work for First Nations Health Authority at Gathering Wisdom VI

Drawing
change

Image credit: [Sam Bradd](#)

Equality

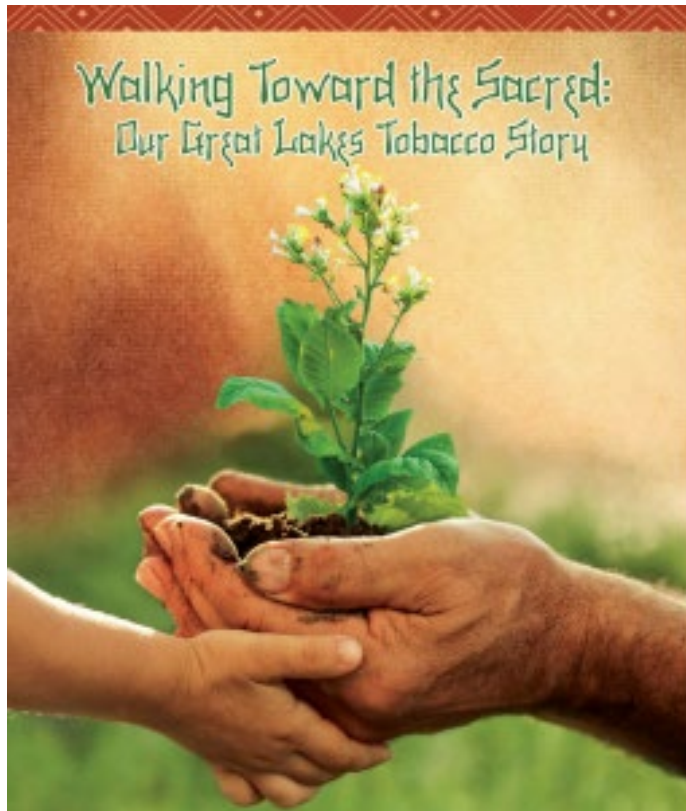


Equity



© 2017 Robert Wood Johnson Foundation.
May be reproduced with attribution.

COMMERCIAL TOBACCO IS NOT TRADITIONAL TOBACCO



[Available at this link](#)



Nicotiana rustica, Solanaceae, Mapacho, flower. Botanical Garden KIT, Karlsruhe, Germany. Wikimedia Commons.

AGENDA

- Overview of E-Registry Laws
- Panel Discussion
- Q&A

AGENDA

- **Overview of E-Registry Laws**
- Panel Discussion
- Q&A

FDA PMTA PROCESS AND OVERVIEW

- New tobacco products need FDA authorization to be sold
- Premarket Tobacco Product Application
- FDA Action

FDA PMTA PROCESS AND OVERVIEW

- New tobacco products need FDA authorization to be sold
 - Approve vs. Authorize
- Premarket Tobacco Product Application
- FDA Action

FDA PMTA PROCESS AND OVERVIEW

- New tobacco products need FDA authorization to be sold
- Premarket Tobacco Product Application
 - Risks and benefits to public health
 - Impact on cessation, tobacco uptake
 - Manufacturing process and safety standards
- FDA Action

FDA PMTA PROCESS AND OVERVIEW

- New tobacco products need FDA authorization to be sold
- Premarket Tobacco Product Application
- FDA Action
 - Marketing Grant Order (authorization)
 - Marketing Denial Order (denial)

FDA PMTA PROCESS AND OVERVIEW

- New tobacco products need FDA authorization to be sold
- Premarket Tobacco Product Application
- FDA Action
 - Marketing Grant Order (authorization)
 - Marketing Denial Order (denial)
 - (FDA/court can stay enforcement)

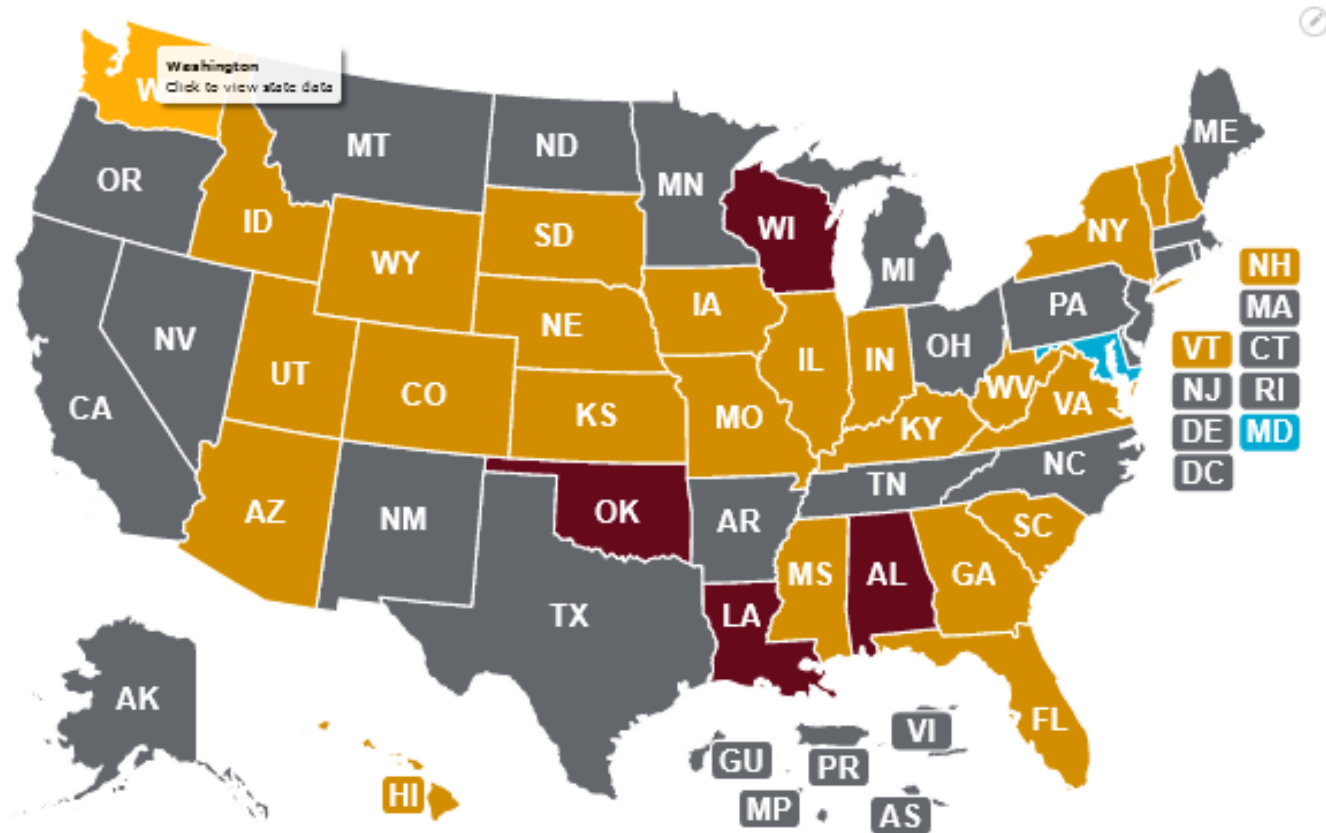
FDA PMTA PROCESS AND OVERVIEW

- New tobacco products need FDA authorization to be sold
- Premarket Tobacco Product Application
- FDA Action
 - Marketing Grant Order (authorization)
 - Marketing Denial Order (denial)
 - (FDA/court can stay enforcement)

Cannot legally market without MGO

OVERVIEW OF E-REGISTRY LAWS

- Red** = Has already passed an e-registry bill
- Gold** = Is considering an e-registry bill
- Blue** = Is considering a public-health-oriented e-registry bill
- Gray** = Does not have an e-registry bill in progress



ANATOMY OF AN E-REGISTRY LAW

Typical E-Registry Bill:

- Public Directory
- Qualify for directory if:
 - Authorized by FDA
 - Submitted PMTA and no definitive denial

1586 Results Export Current Results

< Page 1 of 64 >

Product Name	Manufacturer Name	FDA Order Date	FDA Order Type	Date Added to Directory
OPMH WATSON GOLD 60ML 12MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023
OPMH WATSON (ORIGINAL) 60ML 0MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023
OPMH WATSON WHITE GOLD 60ML 12MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023
OPMH WATSON GOLD 60ML 3MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023
OPMH WATSON (ORIGINAL) 60ML 12MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023
OPMH WATSON (ORIGINAL) 60ML 6MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023
OPMH WATSON PLATINUM 60ML 12MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023
OPMH WATSON GOLD 60ML 0MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023
OPMH WATSON WHITE GOLD 60ML 6MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023
OPMH WATSON (ORIGINAL) 60ML 3MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023
OPMH WATSON WHITE GOLD 60ML 0MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023
OPMH WATSON WHITE GOLD 60ML 3MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023
OPMH WATSON GOLD 60ML 6MG	GRIPUM LLC	5/25/2021	Under Review by FDA	5/18/2023

Scroll for More

<https://myalabamataxes.alabama.gov>

ANATOMY OF AN E-REGISTRY LAW

Public-Health Oriented Approach:

- Public Directory
- Qualify for directory if:
 - Authorized by FDA
 - ~~Submitted PMTA and no definitive denial~~

E-Cigarettes Authorized by the FDA
As of Jan. 2024, these are the only e-cigarettes authorized to be sold in the U.S.

Manufacturer	Product Name
Logic Technology Development LLC	Logic Regular Cartridge/Capsule Package
	Logic Vapeleaf Cartridge/Capsule Package
	Logic Vapeleaf Tobacco Vapor System
	Logic Pro Tobacco e-Liquid Package
	Logic Pro Capsule Tank System (1)
	Logic Pro Capsule Tank System (2)
	Logic Power Tobacco e-Liquid Package
	Logic Power Rechargeable Kit
	NJOY LLC
NJOY DAILY EXTRA Rich Tobacco 6%	
NJOY ACE Device	
NJOY ACE POD Classic Tobacco 2.4%	
NJOY ACE POD Classic Tobacco 5%	
NJOY ACE POD Rich Tobacco 5%	
R.J. Reynolds Vapor Company	Vuse Vibe Power Unit (1)
	Vuse Vibe Tank Original 3.0%
	Vuse Vibe Power Unit (2)
	Vuse Ciro Power Unit (1)
	Vuse Ciro Cartridge Original 1.5%
	Vuse Ciro Power Unit (2)
	Vuse Solo Power Unit
	Vuse Replacement Cartridge Original 4.8% G1
	Vuse Replacement Cartridge Original 4.8% G2

<https://digitalmedia.hhs.gov/tobacco/hosted/E-Cigarettes-Authorized-FDA-Jan24.pdf>

AGENDA

- Overview of E-Registry Laws
- **Panel Discussion**
- Q&A

PANEL DISCUSSION

- Are there important distinctions between the various proposals and laws?
- What do we know about how these laws work in practice?
- What are the public health implications of these bills?
- On balance, should public health advocates support or oppose these bills?

AGENDA

- Overview of E-Registry Laws
- Panel Discussion
- **Q&A**

Questions?

CONTACT US



651.290.7506



publichealthlawcenter@mitchellhamline.edu

Tom.Pryor@mitchellhamline.edu



www.publichealthlawcenter.org



[@phealthlawctr](https://twitter.com/phealthlawctr)



facebook.com/publichealthlawcenter