HEATED CIGARETTES:  
HOW STATES CAN AVOID GETTING BURNED
THE PUBLIC HEALTH LAW CENTER
LEGAL TECHNICAL ASSISTANCE

- Legal Research
- Policy Development, Implementation, Defense
- Publications
- Trainings
- Direct Representation
- Lobby
HEATED CIGARETTES
HOW STATES CAN AVOID GETTING BURNED

• Presenters:
  – Kristy Marynak, MPP, Public Health Analyst, Centers for Disease Control and Prevention
  – Hudson Kingston, JD, LLM, Staff Attorney, Tobacco Control Legal Consortium at the Public Health Law Center
HEATED CIGARETTES
HOW STATES CAN AVOID GETTING BURNED

• Heated cigarettes on the global market
• Distinguishing features
  1. Heating at a temperature lower than conventional cigarettes that produce an inhalable aerosol
     • Heated Cigarettes: 450-700° F (generally)
     • Conventional cigarettes: 1250 – 1300 °F,
     • (max: 1500 °F)
  2. Processed, commercial tobacco leaf is the nicotine source, flavor source, or both
HEATED CIGARETTES
HOW STATES CAN AVOID GETTING BURNED

Federal Regulation
• Pre-Market Review
• Modified Risk Tobacco Product Application
• Vapeleaf
Heated Tobacco Products: Considerations for Public Health Policy and Practice

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LEAD PUBLIC HEALTH ANALYST
CDC OFFICE ON SMOKING AND HEALTH
TOBACCO CONTROL LEGAL CONSORTIUM WEBINAR
AUGUST 2018
The landscape of tobacco products is continually changing.

By being proactive and anticipating new products, we can be comprehensive in our approach to epi/surveillance, health communications, and policy.

Understanding unique properties and health implications of each tobacco product can inform public health planning, policy, and practice.
Cigarette Smoking Is Down...

Adult cigarette smoking prevalence

High school smoking prevalence

Sources: National Health Interview Survey (NHIS). National Youth Risk Behavior Survey.
…But the Tobacco Product Landscape Is Evolving
What Are Heated Tobacco Products?

Contain Tobacco

“Throat-Hit” similar to cigarettes

Positioned to appeal to smokers who have tried and rejected e-cigarettes
Heated Tobacco Product Technology Emerged in the 1980s

FIG. 2: LAUNCH AND WITHDRAWAL FROM THE MARKET OF EARLY GENERATION HEATED TOBACCO PRODUCTS

<table>
<thead>
<tr>
<th>EARLY GENERATION HTPs</th>
<th>LENGTH OF TIME ON THE MARKET</th>
</tr>
</thead>
<tbody>
<tr>
<td>HEATBAR</td>
<td>1 year (1988-1989)</td>
</tr>
<tr>
<td>ACCORD</td>
<td>10 years (1996-2006)</td>
</tr>
<tr>
<td>ECLIPSE</td>
<td>8 years (1998-2006)</td>
</tr>
<tr>
<td>PREMIER</td>
<td>1 year (1988-1989)</td>
</tr>
</tbody>
</table>

WHO
Early prototypes: Flame-activated HTPs

Carbon tip heated with a lighter

User inhales 4-5 times before the tip glows red and product is activated

Packs of 20, similar size and shape of cigarette

Early Prototypes: Electronic HTPs

Test marketing began in 1998 in Richmond, VA, discontinued in 2006 due to “lack of commercial success”

Battery powered “smoking system.” Heating blades pierce Accord cigarette. Device activated only when puffed.

Ads said Accord “produces a lot less smoke” but did not want to “disparage existing brands” in marketing
## Crosswalking Heated Tobacco Products, E-cigarettes, and Conventional Cigarettes

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>HTPs</th>
<th>E-cigarettes</th>
<th>Manufactured Cigarettes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic</td>
<td>✅</td>
<td>✅</td>
<td>✗</td>
</tr>
<tr>
<td>Flame-activated</td>
<td>✅</td>
<td>✗</td>
<td>✅</td>
</tr>
<tr>
<td>Contain tobacco leaf</td>
<td>✅</td>
<td>✗</td>
<td>✅</td>
</tr>
<tr>
<td>Can deliver nicotine</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>Produce secondhand emissions</td>
<td>✅</td>
<td>✅</td>
<td>✅</td>
</tr>
<tr>
<td>Produce smoke</td>
<td>?</td>
<td>✗</td>
<td>✅</td>
</tr>
<tr>
<td>Can deliver marijuana</td>
<td>✅</td>
<td>✅</td>
<td>✗</td>
</tr>
</tbody>
</table>

*Sometimes or always*
In July 2018, FDA announced approval for two R.J. Reynolds Tobacco Company Products, Eclipse and Eclipse Menthol.

FDA categorized the products as “non-combusted cigarettes” because they meet the legal definition of cigarette but “there is evidence that the heat does not reach a level sufficient to cause combustion.”
iQOS is an electronic heated tobacco product manufactured by Philip Morris International (PMI) available for sale in 34 countries as of April 2018.

PMI has submitted applications to FDA for approval to:
- Market iQOS (“Premarket Tobacco Product Application” or PMTA)
- Make health claims (“Modified Risk Tobacco Product” application or MRTP)
**Awareness of Heated Tobacco Product Use Among U.S. Adults, 2017**

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>5.2</td>
</tr>
<tr>
<td>Men</td>
<td>7.0</td>
</tr>
<tr>
<td>Women</td>
<td>3.7</td>
</tr>
<tr>
<td>&lt;30 years</td>
<td>7.6</td>
</tr>
<tr>
<td>≥30 years</td>
<td>4.6</td>
</tr>
<tr>
<td>Non-Hispanic, White</td>
<td>5.1</td>
</tr>
<tr>
<td>Other</td>
<td>5.6</td>
</tr>
<tr>
<td>Current smoker</td>
<td>9.9</td>
</tr>
<tr>
<td>Former smoker</td>
<td>3.7</td>
</tr>
<tr>
<td>Never smoker</td>
<td>4.9</td>
</tr>
</tbody>
</table>

*Source: SummerStyles 2017. Marynak, K et al. Awareness and ever use of “heat-not-burn” tobacco products among U.S. adults, 2017. Accepted by AJPM.*
Ever Use of Heated Tobacco Products Among U.S. Adults, 2017

Percentage (%)

- Overall: 0.7
- Men: 0.8
- Women: 0.6
- <30 years: 1.6
- ≥30 years: 0.5
- Non-Hispanic, White: 0.5
- Other: 1.0
- Current smoker: 2.7
- Former smoker: Relative standard error >40%
- Never smoker: 0.5
Heated Tobacco Product Marketing

Ad for Philip Morris USA’s Accord, 1990s
“Virtually No Lingering Odor, No Ashes”

Ad for Philip Morris International’s iQOS, 2015
“No Fire, No Ash...Less Lingering Smell”

iQOS store outlet in Tokyo, 2015

Sources:
http://www.tobaccoproducts.org/index.php/Accord
ecigintelligence.com;
http://media.corporate-ir.net/media_files/IROL/14/146476/files/index.html
HTPs: Highly profitable replacement for declining cigarette business

iQOS HeatStick revenues $1.55/pk vs <$1.00/pk combustible cigarettes

Major economies of scale

Sticks can be produced on modified cigarette machinery

Lower tax rates

Health implications: Key questions

- Do they burn?
- Is there smoke?
- What are the contents of the smoke/aerosol?
- What are the differences in constituents and use patterns between various product types?
- Will they appeal to youth/young adults/non-tobacco users?
- Will they be used by smokers as a complete substitute for all combusted tobacco products?
Independent studies will provide critically needed information.

One study found that heating tobacco between 100-200°C releases nicotine and some cigarette smoke compounds. Emissions increased with temperature.¹

Another study compared iQOS to a reference cigarette. VOCs, polycyclic aromatic hydrocarbons, and CO were present in iQOS smoke.²

Surgeon General’s Reports offer a public health framework

“The use of products containing nicotine poses dangers to youth, pregnant women, and fetuses. The use of products containing nicotine in any form among youth, including in e-cigarettes, is unsafe.”

– 2016 SGR Conclusion #4

“E-cigarette aerosol is not harmless. It can contain harmful and potentially harmful constituents, including nicotine. Nicotine exposure during adolescence can cause addiction and can harm the developing adolescent brain.”

– 2016 SGR Conclusion #5

“...All products containing tobacco and nicotine should be assumed to be both harmful and addictive...”

– 2014 SGR, Ch. 14, p. 780

“...When there is inadequate or early knowledge, public health decisions should be made on the basis of precaution to prevent harm, rather than on certain risk. This approach requires proof that a product is not harmful—especially for youth—rather than proof that it is harmful.”

– 2016 SGR, Call to Action
Evolving landscape requires continued focus on

- Comprehensive efforts that address all tobacco products, including HTPs and other novel products
- Efforts to prevent youth access and use
- Protection of clean air standards and tobacco-free norms
- Elimination of combusted tobacco use and education about harms of smoking and dual use
- Education about the harms of any tobacco product use, especially for vulnerable populations, such as youth and young adults and pregnant women
- Research and surveillance to understand new products’ impact on the public’s health
Thank you! Questions?
Kristy Marynak
KMarynak@cdc.gov, 770.488.6196

www.cdc.gov/tobacco
HEATED CIGARETTES
STATE DEFINITIONS AND REGULATION
HEATED CIGARETTES
WHAT ARE THEY?

• What the industry calls “heat-not-burn”
• But do they burn?
HEATED CIGARETTES
WHAT ARE THEY?

Two main elements:

• Heating at a temperature lower than conventional cigarettes that produces an inhalable aerosol
  – Heated Cigarettes: 450-700°F (generally)
  – Conventional cigarettes: 1250 – 1300 °F, (max: 1500 °F)

• Contains processed tobacco leaf
  – Used as the nicotine source, the flavor source, or both
HEATED CIGARETTES
WHAT ARE THEY?

Three designs to keep in mind:
HEATED CIGARETTES
WHAT ARE THEY?

Three designs to keep in mind:
50-STATE AND TERRITORIES SURVEY
GENERAL RESULTS

• Smoke-free
  – Very few jurisdictions explicitly cover the use (differs by heated cigarette type)

• Minimum Legal Sales Age
  – Most jurisdictions prohibit the sale to youth (does not differ by type as much)

• Taxation
  – Many jurisdictions could tax them as cigarettes, the rest could tax them as a different tobacco product (room for tax authority interpretation)
SMOKE-FREE LAWS
ARE HEATED CIGARETTES COVERED?

“Smoking means inhaling, exhaling, burning, or carrying or possessing any lighted tobacco product, including cigars, cigarettes, pipe tobacco and any other lighted tobacco product.”
“Smoking means inhaling, exhaling, burning, or carrying or possessing any *lighted* tobacco product, including cigars, cigarettes, pipe tobacco and any other *lighted* tobacco product.”
SMOKE-FREE LAWS
ARE HEATED CIGARETTES COVERED?

“Smoking means the burning of a lighted cigarette, cigar, pipe or any other substance containing tobacco.”
SMOKE-FREE LAWS
ARE HEATED CIGARETTES COVERED?

“Smoking means the *burning* of a *lighted* cigarette, cigar, pipe or any other substance containing tobacco.”
SMOKE-FREE LAWS ARE HEATED CIGARETTES COVERED?

What does “burning” or “lighted” mean?
SMOKE-FREE LAWS
ARE HEATED CIGARETTES COVERED?

What does “burning” or “lighted” mean?

Potential answers from:
• Dictionaries
• Scientific understanding
• Legal precedent from other areas of law
SMOKE-FREE LAWS
ARE HEATED CIGARETTES COVERED?

“Burning”
SMOKE-FREE LAWS
ARE HEATED CIGARETTES COVERED?

“Burning”

Legal definition from arson cases: Courts held burn/burned means any physical change, usually evidenced by charring or blackening, to the structure that was set on fire or was close enough to a heat source to be damaged and charred.
SMOKE-FREE LAWS
ARE HEATED CIGARETTES COVERED?

“Burning”

Legal definition from arson cases: any physical change, usually evidenced by charring or blackening, or close enough to a heat source to be damaged and charred.

Photo credits:
iQOS: https://www.spidersweb.pl/2017/05/iqos-heits-marlboro-philip-morris.html
Revo: screenshot from video: https://www.youtube.com/watch?v=ZBPnkH31zQM
glo: https://heatnotburn.co.uk/inside-the-neostik/
SMOKE-FREE LAWS
ARE HEATED CIGARETTES COVERED?

“Lighted”
SMOKE-FREE LAWS
ARE HEATED CIGARETTES COVERED?

“Lighted”
SMOKE-FREE LAWS
ARE HEATED CIGARETTES COVERED?

“Lighted”

This is sufficient but not necessarily required.
HEATED CIGARETTES
WHAT ARE THEY?

Three designs to keep in mind:
SMOKE-FREE LAWS
ARE HEATED CIGARETTES COVERED?

“Lighted”

VS.

Martin Falbisoner, from Wikimedia Commons

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MINIMUM LEGAL SALES AGE
ARE HEATED CIGARETTES COVERED?

Most states and U.S. territories seem to cover heated cigarettes under definitions including:
“Tobacco product” (often inclusive of “cigarette”)
“Vapor product”
“Alternative nicotine product”
“Electronic nicotine delivery product”
MINIMUM LEGAL SALES AGE
ARE HEATED CIGARETTES COVERED?

Most states and U.S. territories seem to cover heated cigarettes under definitions including:
“Tobacco product” (often inclusive of “cigarette”)
“Vapor product”
“Alternative nicotine product”
“Electronic nicotine delivery product”

…and some states (e.g. UT, CT) forbid providing “tobacco” to minors without defining that term.
TAXATION
ARE HEATED CIGARETTES COVERED?

Coverage as “cigarette” versus coverage as another product.
TAXATION
ARE HEATED CIGARETTES COVERED?

“Cigarette means any roll for smoking made wholly or in part of tobacco irrespective of size or shape and whether or not such tobacco is flavored, adulterated or mixed with any other ingredient, and the wrapper of which is made of paper or any other substance or material except tobacco.”
TAXATION
ARE HEATED CIGARETTES COVERED?

“Cigarette means any roll for smoking made wholly or in part of tobacco irrespective of size or shape and whether or not such tobacco is flavored, adulterated or mixed with any other ingredient, and the wrapper of which is made of paper or any other substance or material except tobacco.”
TAXATION
ARE HEATED CIGARETTES COVERED?

“Cigarette means any roll for smoking made wholly or in part of tobacco irrespective of size or shape and whether or not such tobacco is flavored, adulterated or mixed with any other ingredient, and the **wrapper** of which is made of paper or any other substance or material except tobacco.”
26 U.S.C. § 5702(b)
(b) Cigarette.--“Cigarette” means--
(1) any roll of tobacco wrapped in paper or in any substance not containing tobacco, and
(2) any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1).

27 C.F.R. § 41.11
Small cigarettes. Cigarettes weighing not more than three pounds per thousand.

27 C.F.R. § 41.38
For internal revenue tax purposes, small cigarettes are designated Class A and large cigarettes are designated Class B.
TAXATION

FEDERAL TAX STATUS: CIGARETTES
TAXATION
FEDERAL TAX: PIPE TOBACCO?
HEATED CIGARETTES
WHAT ARE THEY?

Three designs to keep in mind:
THE “AVERAGE” STATE
WHERE THE LAW IS AMBIGUOUS

In State X the Minimum Legal Sales Age is 21 and covers “tobacco products in any form” but both the smoke-free standard and tax definition are ambiguous. How might a policymaker address this ambiguity?
Current law:
“Smoking” means inhaling, exhaling, burning, or carrying any lighted cigar, cigarette, or pipe, or any other lighted tobacco, nicotine, or plant product intended for inhalation, including hookah and marijuana, whether natural or synthetic. “Smoking” also includes the use of an electronic smoking device.
Current law:
“Smoking” means inhaling, exhaling, burning, or carrying any lighted or heated cigar, cigarette, or pipe, or any other lighted or heated tobacco, nicotine, or plant product intended for inhalation, including hookah and marijuana, whether natural or synthetic. “Smoking” also includes the use of an electronic smoking device.
Clarifying language: “Smoking” means inhaling, exhaling, burning, or carrying any lighted, *heated, or activated* cigar, cigarette, or pipe, or any other lighted, *heated, or activated* tobacco, nicotine, or plant product intended for inhalation, including hookah and marijuana, whether natural or synthetic. “Smoking” also includes the use of an electronic smoking device.
Ambiguous terms in definition of “cigarette:”

for smoking (does not appear in federal law)

wrapped → “covered” (24 states use “covered”)

roll → define or expand to include future products
HEATED CIGARETTES
SURVEY AND FACT SHEET

Hot off the presses – August 2018
IN YOUR JURISDICTION
ARE HEATED CIGARETTES COVERED?

If you aren’t sure please get in touch.

- Legal Research
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