Smoking Harm Reduction: If Not Now When?

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Outline for my talk

- Historical context, 1950-2000
- How things have changed since 2000
- Capitalism to advance tobacco control
- Next steps forward
Historical context

...this is an old question
1950’s

1950s Tar Derby
“Harm Reduction?”
The truth is out:

The wire services recently released a new report that revealed new TRUE Filter Cigarettes delivered less tar and nicotine than other brands tested...

It's TRUE... without our knowledge or permission, these tests were conducted and TRUE Filter Cigarettes were found to be "most effective in reducing tar and nicotine" of the twelve brands tested. Tar, 16.9 mgs. Nicotine, 8.79 mgs.

It's TRUE... our air-filtration system combines a working filter, suction vents and mouthpiece to help reduce solids in the smoke.

It's TRUE... an unusually fine blend of lighter tobaccos chosen for low tar and nicotine content are used in the making of TRUE. And yet it is also true that TRUE has exceptionally good taste.

Now that the truth is out, shouldn't your brand be TRUE?

Available everywhere soon.

1966

Source: http://industrydocuments.library.ucsf.edu/tobacco/docs/kgih003.pdf

1971
Twelve Year Effort Ends With Unprecedented Flavor In Low Tar Smoke.

New Enriched Flavor discovery for 9 mg. tar MERIT achieves taste of cigarettes having 60% more tar.

Taste Tested By People Like You.

Key Flavor Ingredients Of Tobacco Isolated

By isolating certain "key" flavor ingredients of tobacco in cigarette smoke, ingredients that deliver taste was out of proportion to tar, researchers at Philip Morris have developed a way to pack extra flavor into tobacco without the usual increase in tar.

The discovery is called Enriched Flavor. It's- extra flavor. Natural flavor Flavor that can't burn out, can't fade out, can't do anything but come through for you.

We packed MERIT with Enriched Flavor and began a series of taste-tests.

Merit and Merit Menthol

MERIT Filtered
MERIT Menthol

Surgeon General's Warning: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy.
FDA Commissioner David Kessler, MD, asserts the FDA's jurisdiction over tobacco products by declaring nicotine a drug. [25] President Clinton approves this proposal, but in 2000 the US Supreme Court rules that the FDA cannot regulate tobacco products without being given the power to do so by Congress.
Sullied Public image

Tobacco Chiefs say Cigarettes Aren’t Addictive, April 1994
1996 Nicotine Medications available OTC
Also, in the early 1990s, a class action lawsuit suit is filed on behalf of injured Florida smokers, resulting in the longest civil trial in American history...

Dr. Howard Engle

$145 billion verdict

Stanley and Susan Rosenblatt

"Every lawyer Susan and I ever discussed this with said 'Rosenblatt, you're out of your mind,' ... This was like taking on a country, taking on the tobacco industry.'"
- Stanley Rosenblatt

Miami courthouse

18 month long trial
State Reimbursement Cases

1994-1998
Mississippi $3.6 B
Florida: $11.3 B
Texas $14 B
Minnesota $6.1 B

1998: 46 States and the tobacco companies settle. Master Settlement Agreement (MSA)

1998 Minnesota and BCBS vs. Philip Morris et al.
Settled $6B over 25 years
+ 200M annually
35 Million Pages

Depositories
BAT - Guildford, England
US - Minnesota
What has changed since 2000?
Industry evolution

- Consolidation
- Globalization
- Diversification
- Profits
NEW PRODUCTS TO COMPETE WITH CIGARETTES
Tobacco Lozenges Seek FDA Stamp

Star Scientific Asks Agency to Certify New Smokeless Product as a ‘Modified Risk’

BY DAVID KESMODEL

Star Scientific Inc. said it filed the first application with the U.S. Food and Drug Administration to have a tobacco product certified as being less harmful than traditional forms of tobacco.

Star requested Friday that Ariva-BDL, a dissolvable tobacco lozenge with wintergreen flavoring, be approved as a “modified risk” product under the Family Smoking Prevention and Tobacco Control Act. The landmark law, enacted last year, gave the FDA broad authority to regulate the industry.

The filing by Star, a small publicly traded company based in Glen Allen, Va., is expected to be one of many such applications that will be filed by tobacco purveyors in the coming months. The FDA has said it is looking to approve such products by the end of the year.

Star Scientific’s Ariva nicotine lozenges remain a small subcategory in the smokeless-tobacco segment.
Can capitalism advance the goals of tobacco control?

The dream of a tobacco-free society is not going to happen any time soon. Competition to produce a less toxic more consumer-acceptable delivery system for nicotine would benefit the goals of public health. At present there is no real competition, as the cigarette cartel is dominated by a small group of companies who have little incentive to change the status quo. Competition to produce more consumer-acceptable medicinal nicotine products would be helped by educating consumers about what factors in tobacco products really contribute to disease risk. Ironically, many smokers do not perceive much difference in health risk between smokeless tobacco products, nicotine medications and cigarettes.

Commentary in: Addiction, 97, 957-62, 2002
E-cigs on the rise

Smoke without fire
Suck on an e-cigarette and it produces a cloud of nicotine-carrying vapour with none of the toxic by-products of burning tobacco.

E-cigarette Strength an Incremental Secular Volume Headwind (2013 MSE ~0.5%)

YoY Chg in Stick Equivalents (e-cigarettes, Bn) % of Prior-Year Cigarette Volumes

Source: Company Data, Morgan Stanley Research
A nicotine-limiting standard could make cigarettes minimally addictive or nonaddictive, helping current users of combustible cigarettes to quit and allowing most future users to avoid becoming addicted and proceeding to regular use.

A Nicotine-Focused Framework for Public Health
Scott Gottlieb, M.D., and Mitchell Zeller, J.D.

July 28, 2017

To truly protect the public, the FDA’s approach must take into account the continuum of risk for nicotine-containing products.
Basic Principle

Less harmful products should have a competitive advantage.
Public support for regulating nicotine in cigarettes

If you could get nicotine in products other than tobacco would you support or oppose a law that reduced the amount of nicotine in cigarettes and tobacco, to make them less addictive?

Support for low nicotine cigarettes of smokers by country (%)

- **Canada**
  - Daily Smoker: 68%
  - Non-Daily Smoker: 73%
  - Total: N=3205

- **United States**
  - Daily Smoker: 54%
  - Non-Daily Smoker: 56%
  - Total: N=2296

- **England**
  - Daily Smoker: 57%
  - Non-Daily Smoker: 68%
  - Total: N=3865
Four Avenues of Health Interventions

1. Prevention – keep nonsmokers from starting
2. Cessation – help smokers to quit
3. Protection of Third Parties – 2nd-hand smoke, fires
4. Reduced risk - alternative nicotine products
Failure to Play all Four Suits in the deck is NOT a Winning Strategy!

- Avoids reliance on one-off gains
  - Hike in cigarette taxes
  - Passage of a clean indoor air law
  - New pack warnings

- Misses synergies between strategies
  - Exploiting cross-elasticities
    - Adding ‘Facilitation’ to ‘Motivation’
Can low-risk nicotine products further reduce deaths from smoking?
Yikes…what are we telling the public

“We want parents to know that nicotine is dangerous for kids at any age, whether it’s an e-cigarette, hookah, cigarette or cigar,”

“…Nicotine exposure at a young age may cause lasting harm to brain development, promote addiction, and lead to sustained tobacco use.”

Henningfield Response (New York Times, April 18, 2015):
“putting electronic products in the Same basket as cigarettes is not truthful, credible or helpful.”
Figure 1. Monitoring the Future Survey, Last 30-Day Cigarette Prevalence, High School 12th-Grade Students, Pre-Vaping Trend (2002-2013) with Vaping Estimates (2014-2017)

\[ y = -0.8738x + 1775.3 \]
\[ R^2 = 0.9733 \]
U.S. Cigarette Volumes Have Deteriorated

Figure 11 shows why we are so concerned about U.S. tobacco. The blue line shows the most accurate number we have of the underlying quarterly volume shrinkage for cigarettes: it is the adjusted figure for the industry, as reported by Altria. The red line is the Nielsen figure for U.S. cigarette volumes. The critical point is that for the first quarter of 2018, Nielsen is recording cigarette volumes of about -6%. Figure 11 also shows that since 3Q14, Nielsen has been a very good predictor of the overall market, although it has generally been too optimistic.

Figure 11. U.S. Cigarette Volumes – Nielsen Suggests Volumes Have Gotten a Lot Worse in 2018

Note: Altria’s data is adjusted for inventory and other effects. *1Q18 up to March 24. Source: Company Reports and Nielsen.
We think JUUL is disrupting the industry

The 2-year stack in Figure 2 shows the decline in volumes started to accelerate in 4Q17, as opposed to the start of 2018. We think the best explanation is the sudden acceleration in the growth of JUUL which occurred around October / November 2017. This is shown in Figure 3 but it is important to realize Figure 3 (and Figure 4) understate the importance of e-vapor and JUUL, as they only show Nielsen data, which probably captures considerably less than half of e-vapor sales.
New Products May Worsen the Disruption

So far we have said that U.S. cigarette volumes have been falling faster in Nielsen since about December 2017, as JUUL accelerated.

The trouble is that we think pod-based e-vapor systems will grow even faster in the rest of this year as two new products – Altria’s MarkTen Elite and Imperial’s myBlu – hit the market, potentially hurting cigarette volumes further. Both are very similar to JUUL, and both are being ramped up currently:

- Altria’s MarkTen Elite has been in about 6,000 stores in the U.S. since February and on-line.
- Imperial is rolling out myBlu nationwide, starting with its website.

Both products are decent competitors to JUUL, and both are being sold by organizations with huge distribution muscle. Furthermore they are being sold at a discount: a JUUL starter pack is $49.99 but both MarkTen Elite and myBlu packs are available at $19.99.
PRESS RELEASE

Leading Health And Medical Groups Urge Immediate FDA Action To Address Rising Youth Use Of Juul E-Cigarettes

April 18, 2018

WASHINGTON, D.C. – Six leading public health and medical organizations today urged the U.S. Food and Drug Administration to take strong and immediate action to address the dramatic rise in teen use of Juul electronic cigarettes, which has been widely reported by media and educators across the United States.
Try to listen and work together...

Public health groups and the vaping industry need to listen to each other so they can work together on regulations & policies that depress cigarette sales while also providing smokers access to safer alternative nicotine products.
Action Steps

Embrace policies that further disrupt the cigarette market:

Product regulations

- very low nicotine standard for combustibles
- enhanced product warnings on combustibles
- standardized product features, i.e., length, weight, filter design, packaging

Support higher taxes on combustible products
Possible actions steps

Embrace vaping product standards
- Safety standards for products
- Limits on marketing
  - Adult smokers only (21+ years)
- Accurate labelling
- Inform consumers of risks and benefits

Accept some product taxation
Possible Action steps

Support a common research agenda to evaluate the risks and benefits of vaping

– Indication for smoking cessation
– Indication for reduced harm
– Use in special populations
  • Youth
  • High risk smokers
  • Low income
We need to ask the right questions?

- Which groups in the population are likely to benefit most from the transition from cigarettes to alternative nicotine products? Why?

- What groups may be harmed by transitioning away from lower risk alternative nicotine products? Why?

- How do we design lower risk products and marketing strategies that optimize population health benefits and minimize harms?

- What policies would accelerate competition for the marketing of lower risk nicotine products?
Any Questions?