# Investor Day | 14 March 2019

BRITISH AMERICAN TOBACCO

# A THRIVING BUSINESS UNDER CURRENT AND FUTURE REGULATION IN THE U.S.

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Our vapour product Vuse, and oral products Grizzly, Camel Snus and Kodiak, which are only sold in the US, are subject to FDA regulation and no reduced-risk claims will be made to these products without agency clearance.

**Revision**

For presentation purposes within this presentation, all prior periods have been revised to be consistent with the current reporting structure. All of the information in this presentation is in respect to continuing operations, revised for the fully retrospective adoption of IFRS 15.

# JIM FIGLAR

## EVP R&D AND SCIENTIFIC & REGULATORY AFFAIRS

- **20 Yrs** Industry experience
- Ph.D. in Chemistry
- SVP Scientific & Regulatory Affairs
- Research Scientist
- Litigation & Regulatory Representative
- Leads U.S. Product Innovation

# Key Topics

1. Proposed FDA Standards
2. Managing the Regulatory Process
3. The Rulemaking Process
4. Our Vapour Recommendations to FDA
5. A Menthol Regulations Deeper Dive
6. Conclusions

# Proposed FDA Standards

# Proposed Nicotine Standard

- We believe the Current Proposed Standard is not justified or workable

**Why?**

1. A non-zero, non-addictive threshold has not been scientifically established
2. Laboratory or Pilot scale testing does not equate to commercial viability
3. Compliance measures have not been established
4. Premise indicating new entrants will not use these products is untested
5. Premise that current consumers will not use these products is untested
6. Unintended consequences: Economics, Agriculture, Societal, Illicit Trade

- FDA must address all of the above definitively before a final rule can be promulgated, which is why we told the FDA it would take 20 years to comply with such a standard.

# Proposed Menthol Ban

- We believe a Proposed Ban on Menthol Cigarettes is not justified or workable

**Why?**

1. Non-menthol cigarettes carry the same health risks as menthol cigarettes
2. Science to date on initiation, cessation, dependence and progression is not compelling
3. Public Health benefits have not been projected or tested
4. Unintended consequences: Economics, Agriculture, Societal, Illicit Trade

- FDA must address all of the above definitively before a final rule can be promulgated. On issues like societal impacts or self-mentholation, the agency has not begun the necessary work to address those concerns.

# Enforcement Discretion on Retail Vapour Sales

- On March 13, FDA released changes to their guidance regarding vapour products

**What?**

1. Bringing forward the PMTA deadline to 2021 on flavors
2. Flavored products other than tobacco, mint and menthol: on sale in age restricted outlets only
3. On-line sales must be limited
4. On-line sales require third party  age verification

- FDA intends to exercise enforcement discretion 30 days after guidance is finalized. The FDA has opened up a comment period for 30days.

# Managing the Regulatory Process

# FDA regulatory process | What is possible

## FDA CAN:

- ☑ **Issue Guidance** (while it is not strictly binding, FDA uses guidance as its "best thinking" when reviewing applications)
- ☑ **Issue Rules** through the rule-making process
- ☑ **Exercise Enforcement discretion**
- ☑ **Conduct Facility Inspections** (2-year cycle)
- ☑ Issue **Tobacco Product Manufacturing Procedures** (GMPs)
- ☑ Issue Non-compliance **Fines / Penalties**

## FDA CANNOT:

- X Reduce nicotine in tobacco products **to zero**
- X **Ban a category of product**
- X **Institute rules that dictate agricultural practices**

***FDA is constrained by Judicial Review via constitutional protections and precedent***

Source: Company data

# What are the key roles of tobacco product regulation?

STRONG PRODUCT REGULATION ACROSS THE WHOLE TOBACCO PRODUCT LANDSCAPE CAN:

**PROTECT CONSUMERS**

- Educate & minimize risk to consumers
- Prevent rogue or unsubstantiated product claims
- Ensure product consistency and quality

**ENSURES BEST-IN-CLASS**

- Compliance demands serious Product & Category knowledge
- Effectively segregate serious players from the pretenders

SUCCESSFUL NAVIGATION OF THE REGULATORY LANDSCAPE REQUIRES:

**Supply chain flexibility**
Interchangeable materials, top tier material approvals

**Robust product design**
Safety, consistency, quality measures

**Product knowledge & data**
Performance, chronic and acute impact to consumers and society

**Innovation**
New products to meet both consumer and regulatory needs

**Engagement**
More than "filling out a form"

BAT IS WELL POSITIONED TO THRIVE UNDER SUCH A LANDSCAPE:
WE HAVE THE PEOPLE, THE EXPERIENCE AND DEMONSTRABLE TRACK RECORD OF SUCCESS

# What regulation based on the risk continuum would look like

**REGULATION & REGULATORY BODIES SHOULD SUPPORT THE RISK CONTINUUM THROUGH:**

- Active **CONSUMER EDUCATION PROGRAMS** to correct misperceptions (nicotine, relative risk differences by category, etc.)
- **CLEAR RULE-MAKING with HIGH, but achievable STANDARDS** (including improved prevention measures to address underage adoption of tobacco products)
- **RAPID** and **TRANSPARENT REVIEW of applications**

***Effective Regulation based on the above will not only allow for innovative PRRP's to flourish, they could propagate a rapid and transformative benefit to Public Health***

# FDA Rulemaking Process

# FDA Announcements and Rulemaking Process

CURRENT STATUS:

- **July 2017:** FDA announced plans to explore a reduction in nicotine levels
- **March 2018:** ANPRM's on Nicotine Standards and Flavors in ENDs Products
- **Nov 2018:** FDA announced plans to relook at a menthol ban and flavoured cigars

**REMINDER**

FDA RUNS THROUGH A MULTI YEAR, SCIENCE BASED, ITERATIVE, PUBLIC, SET OF PROCESSES:

- 9 step process


- All Final Rules must adequately address Substantive Comments to the Docket

***No formal proposed rule(s) has made it through the Office of Management and Budget***

Source: Company data

# Our topline views on FDA Rulemaking

## PROS:

- ☑ FDA seems committed to regulating through the **rule making process**
- ☑ FDA may be signaling a shift from regulating via "guidance" which is **neither stable, predictable or transparent vs. regulation by rulemaking**
- ☑ FDA must take account of **solid science**

## CONS:

- ~ FDA is **not immune to public pressure**
- ~ Companies have to **bridge the "trust" gap**
- ~ FDA remains **less critical of information** generated **by Public Health**

# Recommendations on Vapour

# We support clear, science-based regulation for Vapour

## OUR VAPOUR MARKET COMMITMENTS AND RECOMMENDATIONS TO FDA…

### TO ADDRESS YOUTH APPEAL:

- Retailer Education & Support
- E-Commerce Age-Verification
- Responsible Marketing Practices
- Right Decisions. Right Now. (Youth Prevention Program)

### RECOMMENDATIONS TO MONITOR & REGULATE THE MARKET (SHARED WITH FDA):

- 8th August 2022 date for PMTA submissions
- Descriptive Flavor naming conventions to minimise youth appeal
- Abbreviated PMTA/Plan for November HPHC submission deadline to identify serious players
- Recommended joint FDA/Industry meetings to agree on retail monitoring and data collection

# Menthol Regulations Deeper Dive

# **Menthol** | Headlines vs bottom lines

## Headlines:

On November 15, 2018 FDA Commissioner Scott Gottlieb during a media event focused on the "Teen Epidemic" regarding the rise in use of Vapour products by youth made an additional and unexpected announcement around the possibility of banning menthol in cigarettes

## Bottom Line:

This issue was debated for several years after the Tobacco Control Act became law in 2009
FDA issued a report in early 2013 with no definitive actions associated
The ANPRM released in Spring of 2018 (Flavors in e-Cigarettes) also requested updated information related to menthol, menthol in combustible cigarettes, etc.

## Current State of Play:

Any action to limit or remove menthol will REQUIRE FDA to scientifically evaluate the impact on:

**Sensitive populations:**
*85% of African American smokers: smoke menthol*

**Social justice**

Potential rise of **illicit trade**

Source: Company data

# **Menthol** | Areas of agreement with FDA

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA'S 2013 MENTHOL EVALUATION:

| | |
|---|---|
| **SMOKE CHEMISTRY & TOXICOLOGY** | *"…the weight of evidence supports the conclusion that, from a nonclinical toxicity standpoint, menthol in cigarettes is* ***not associated* with increased or decreased smoke toxicity****."* |
| **SMOKE EXPOSURES** | *"…the weight of the evidence supports the conclusion that menthol in cigarettes* ***is likely not associated* with increased or decreased levels of biomarkers of exposure****."* |
| **EPIDEMIOLOGY** | *"…the weight of the evidence supports the conclusion that menthol in cigarettes is* ***not associated* with an increase in disease risk*** *to the user compared to nonmenthol cigarette smokers."* |

* **Clarifying Point:** "*not associated*" means scientific justification is clear and definitive; "*likely not associated*" means more science is needed to be definitive

# **Menthol** | Areas of challenge to FDA

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA'S 2013 MENTHOL EVALUATION:

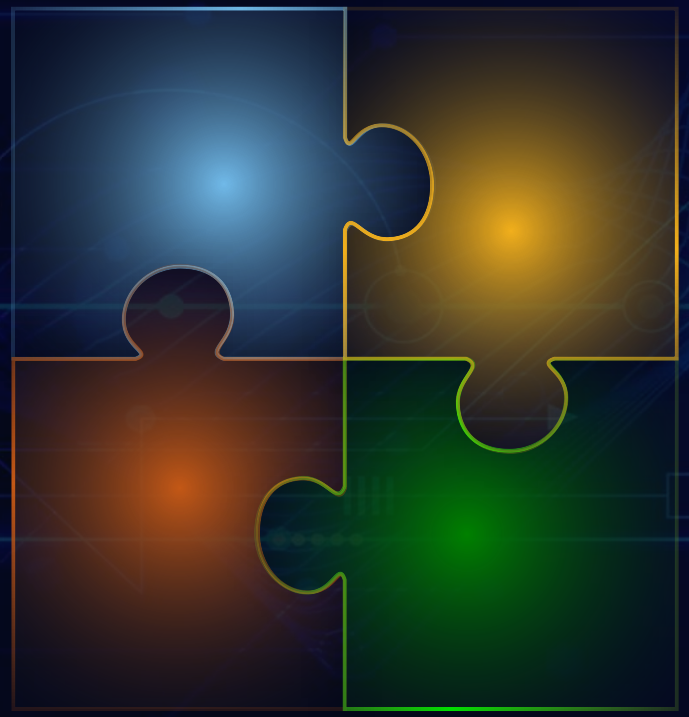
*"the weight of evidence supports the conclusion that menthol in cigarettes is **likely associated*** with… **increased initiation and progression to regular cigarette smoking, increased dependence, and reduced success in smoking cessation."***

* **Clarifying Point:** "likely associated" means more scientific justification is needed before a definitive conclusion can be reached

# **Menthol** | BAT addressed FDA's areas of concern with the latest scientific information on:

SMOKING PROGRESSION

DEPENDENCE



SMOKING CESSATION

SMOKING INITIATION

*Comments available at https://www.regulations.gov/document?D=FDA-2017-N-6565-18265. Our summaries focused on nationally representative adjusted analyses, a comprehensive review of existing science also supports these views, that review will be submitted for peer reviewed publication in 2019.

# Conclusion

***The FDA regulatory approach has to be science-driven and evidence based***

- BAT has the **people, experience and successful track record to thrive under such a landscape**
- No formal FDA rules on Combustibles Product Standards have passed the office of Management & Budget
  - Any action will require FDA to scientifically evaluate the impact on: **sensitive populations, social justice impacts, economic impact and the potential rise of illicit trade**
  - We have **recently addressed FDA's areas of concern with the latest scientific information**
- **We support science-based regulation for Vapour**, have made recommendations to FDA to regulate the market and have clear commitments to address youth appeal

***We expect to sustain a thriving business under current and future regulation in the US***