Regulation: when less is more
WHO – 1 billion deaths

Projected Deaths
Caused by Tobacco Use
During the 21st Century
Total 1 Billion

I smoked for 45 years and tried every NRT product available, none of them worked. I continued to smoke even though my health was getting worse, resulting in COPD and using oxygen daily.

September 2011 I discovered e-cigarettes and they worked. It was like someone handed me a miracle. In less than a week I stopped using regular cigarettes. I haven’t had a tobacco cigarette since.
From WHO Tobacco Atlas 2006 edition

### 2000–2010

**Number of smokers, billions**
- 1.3
- 1.6
- 1.4
- 1.4
- 1.8

### 2010–2020

- 1.4
- 1.6

### 2020–2030

- 1.6

### 2030–2040

- 2.0

### 2040–2050

- 2.2
- 1.5

### Health

- Tobacco kills more than 5 million people annually, accounting for 6% of all global deaths and 4% of disabilities.
- Almost 700 million children are exposed to passive smoking.

### Economics

- Global annual economic cost (health-care costs plus costs to the economy) of tobacco: US$130 billion a year by 2010.

### The Tobacco Industry

- Industry consolidation leads to two to three huge companies that dominate global sales.
- Huge advances are made in genetics. Tobacco plants are engineered to produce vaccines and other beneficial products.

### Action Taken

- WHO Framework Convention on Tobacco Control (FCTC) is ratified by most countries.
- Tobacco advertising and promotion is eliminated worldwide.
- Tobacco control funded from a percentage of tobacco tax in most countries.
- Duty-free tobacco no longer exists.
- New, commercially profitable uses for tobacco are developed.

### Future

- The future is uncertain. Some of these assets may never occur.
The Endgame?

Projected global adult population growth

Billion adults > 15 years

The endgame?

Scenarios for future smoker population

Scenario – 15% global prevalence by 2050

Constant prevalence (28%)
The endgame?

Scenarios for future smoker population

- Constant prevalence (28%)
- Global smoking prevalence declines to 15%

Billion adults > 15 years

Scenario – 15% global prevalence by 2050
If all goes well

Scenarios for future smoker population

- Constant prevalence (28%)
- Global smoking prevalence declines to 15%
- Contested by tobacco control

HARM
The endgame – a nicotine product contest?

Scenarios for future nicotine markets

Constant prevalence (28%)

Global nicotine prevalence declines to 15%

Contested by tobacco control

Contested by nicotine products

Billion adults > 15 years

2010 2015 2020 2025 2030 2035 2040 2045 2050
How far could low-risk nicotine products go?

Scenarios for future nicotine markets

- Constant prevalence (28%)
- Global nicotine prevalence declines to 15%
- Global smoking prevalence declines to 5%

- Contested by tobacco control
- Contested by low risk nicotine products
- Cigarettes and other combustible tobacco
How far could low-risk nicotine products go?

Scenarios for future nicotine markets

This boundary matters most for public health
The endgame: analyst view

Consumption of e-cigs may overtake traditional cigarettes in the next decade ... and they’ll only evolve and improve as time goes forward.

Bonnie Herzog, Wells Fargo Securities, 2013
The endgame: analyst view

Consumption of e-cigs may overtake traditional cigarettes in the next decade ... and they’ll only evolve and improve as time goes forward.

Bonnie Herzog, Wells Fargo Securities, 2013
"Modified Herzog scenario" for future nicotine markets

- Constant prevalence (28%)
- Global nicotine prevalence declines to 15%
- Global smoking prevalence declines to 5%

"E-cigarettes overtake cigarettes by 2030"
Who is this?

Mitch Zeller
(now) Director of the Center for Tobacco Products
FDA

Key messages

- Any evaluation of endgame strategies must start from the premise that there is a continuum of risk associated with nicotine-delivering products.
- Strategies should be pursued that encourage the use of the cleanest and safest form of nicotine delivery.
- Product regulation can play an important rule in any endgame approach.
Harm reduction equation

Harm reduction = Reduced risk \times Number who switch

Product toxicity & other risks

Product attractiveness

Consumer preference
Harm reduction equation

Harm reduction = Reduced risk \times \text{Number who switch}

Product toxicity & other risks

Product attractiveness

Consumer preference
Harm reduction categories – risk estimates

Crude estimate of risk – Cigs = 100

- Cigarettes
- Heat not burn
- Smokeless
- E-cigs
- NRT
Focus on the right relative risk

More regulation
Lower risk

regulated e-cig

"unregulated" e-cig

e-cigarettes

cigarette
Harm reduction equation

Harm reduction = Reduced risk \times Number who switch

Product toxicity & other risks

Product attractiveness

Consumer preference
Analysts

We remain very bullish on the vast potential of e-cigs given the rapid pace of innovation. [We believe] that the benefits of e-cigs are becoming increasingly apparent to consumers, helping to drive trial and repeat purchases aided by stepped-up advertising and a lot of internet “buzz”

Wells Fargo
Regulation comes at a price

- Reduced appeal
- Increased cost
- Greatly reduced variety & niche products
- Slower innovation pace
- Fewer, duller innovations
- Less personalisation
- Boring branding & marketing
- Trusted brands & firms destroyed
- Oligopoly & reduced competition
- Black market, DIY
- Fewer, duller innovations
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Reduced appeal
Harm reduction equation

\text{Harm reduction} = \text{Reduced risk} \times \text{Number who switch}

\text{Trade offs}

\textbf{Conclusion 1.} The perfectly risk free product that no-one wants scores badly in the harm reduction equation

\textbf{Conclusion 2.} A diverse range of products with substantially reduced risk lets each smoker decide which product is best
Triple negative

Tough on harm reduction
Specialised medicines language

- Consistent drug dosing
- Adverse drug reactions
- Safety
- Quality
- Efficacy
- Treats or prevents disease
## Getting tough on harm reduction?

<table>
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<th><strong>Counter-productive</strong></th>
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<td>Pharmacies / as tobacco</td>
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<td>Age restrictions</td>
<td>Adults</td>
<td>Makes little real difference</td>
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<tr>
<td>Taxation</td>
<td>Like tobacco</td>
<td>Fiscal incentive to switch</td>
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What do analysts think...?

We believe many current suppliers would struggle to meet medical standards, and for the UK they may have to by 2016. Big players with deeper pockets would survive and prices could rise – a hugely preferable outcome for Tobacco.

**BNP Paribas**

Tougher regulation, as well as providing a relative advantage to their e-cigarette divisions, would result in higher prices for e-cigarettes – which could also benefit tobacco companies by limiting their attraction for smokers and slowing the decline in tobacco sales.

**Fitch**
What do analysts think…?

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BNP Paribas

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Fitch
European Parliament – amendment 170

- Requires medicines regulation if claim made
- Requires Article 17 notification regime otherwise
- Emphasises general safety requirement
- Applies Article 16 – cross border distance sales
- Applies advertising directive 2003/33/EC and audiovisual services 2010/13/EU
- Information leaflet
- Warning “this product is intended for use by existing smokers. It contains nicotine which is a highly addictive substance”
- Warning size - 30% or 40% (Council =30%) and specification from Article 10
- 30mg/ml threshold – “are not placed on the market” (medicine)
- Age restriction (no less than 18)
- Restriction on additives – application of Article 6.4 (vitamins etc)
- No tobacco branding
- Allows flavourings
- Requires sales allowed ‘outside pharmacies’
- Review
Purpose built regulation for e-cigs / NCPs

1. Accountabilities – responsible person
2. Disclosure and notification regime
3. Labeling and consumer information
4. Safety assessment and product file
5. Contaminants / purity
6. Prohibited ingredients
7. Specific standards for vaping devices CEN/ISO
8. Updating: review & technical committee
9. Marketing (like alcohol?) – mostly member state
10. Retail sales age restriction – member states
11. ... public vaping?
Harm reduction equation with population effects

Harm reduction = Reduced risk \times Number who switch

- Extra smokers + Extra quitters

Gateway to smoking
Dual use
Reduced quitting
Normalising smoking

Gateway exits
Complete cessation
Extra quitting
Normalising non-smoking
Conclusion

- Be positive about the (vast) potential
- Put the (minor) risks in perspective
- Regulate as though the 1 billion matter most
Thank you...

Counterfactual