

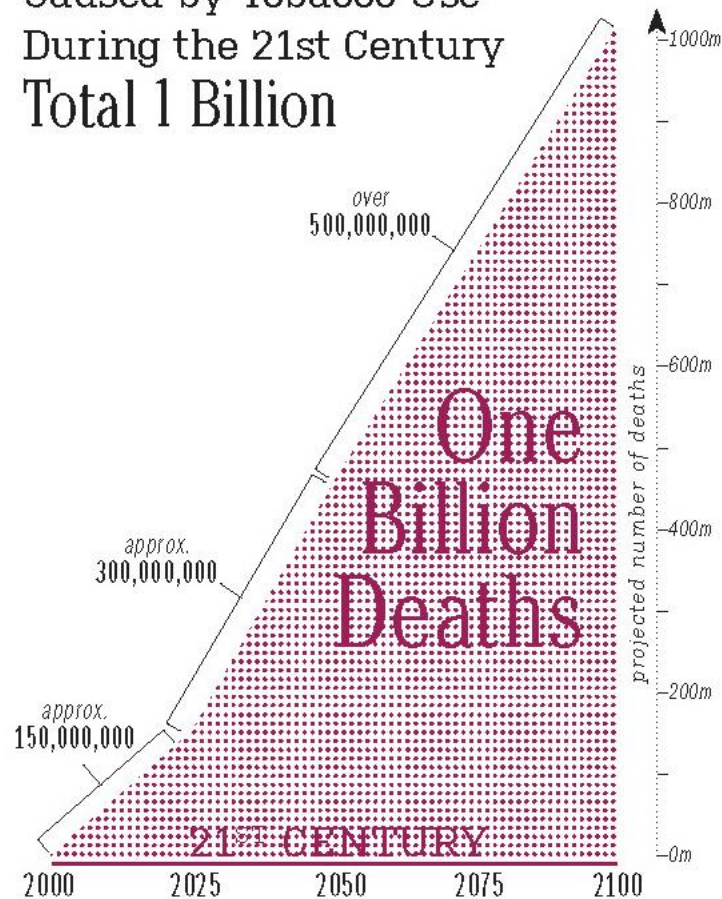
Regulation: when less is more



Counterfactual

WHO – 1 billion deaths

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



source: Tobacco Atlas 4th edition; tobaccoatlas.org



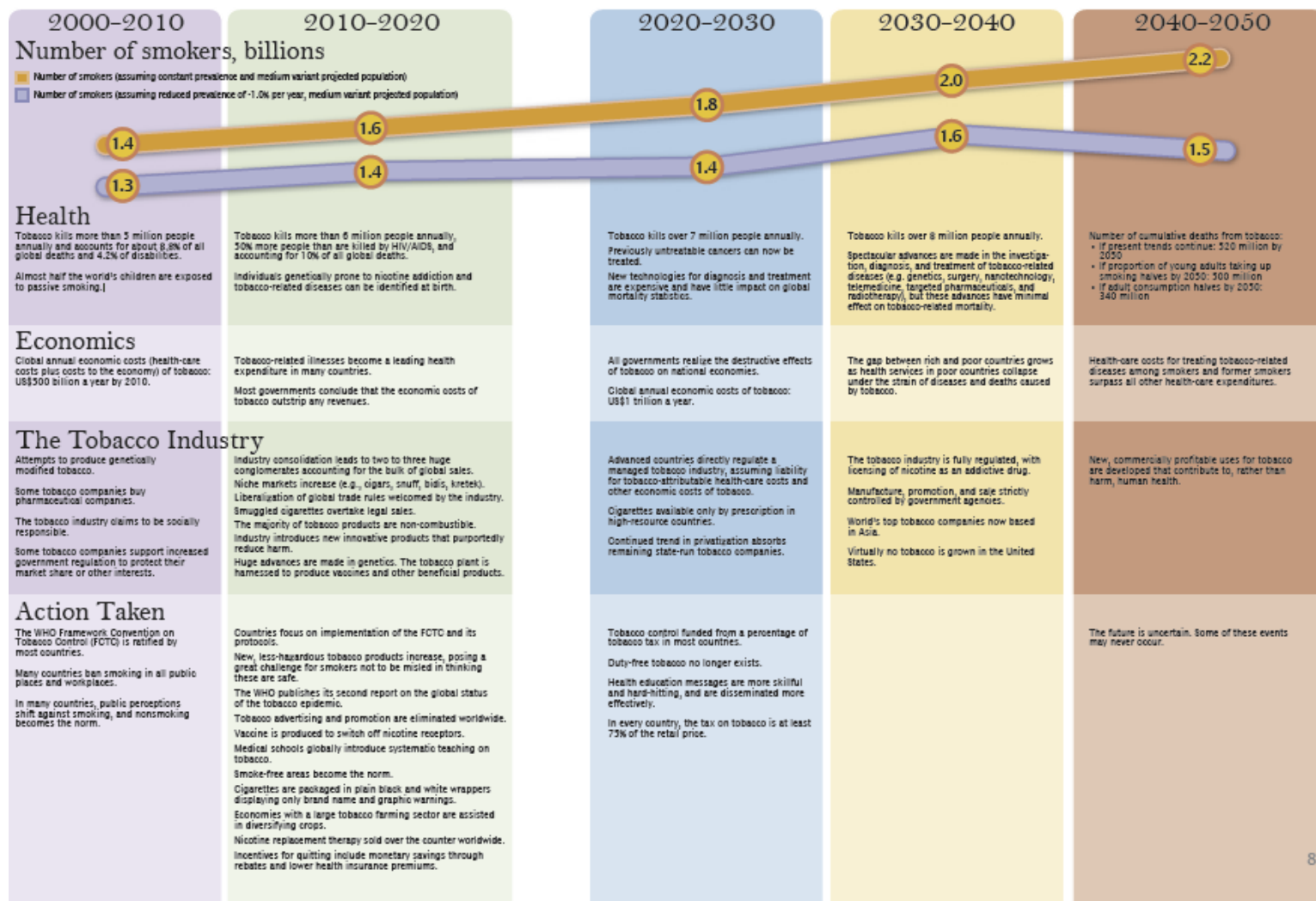
One billion



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.

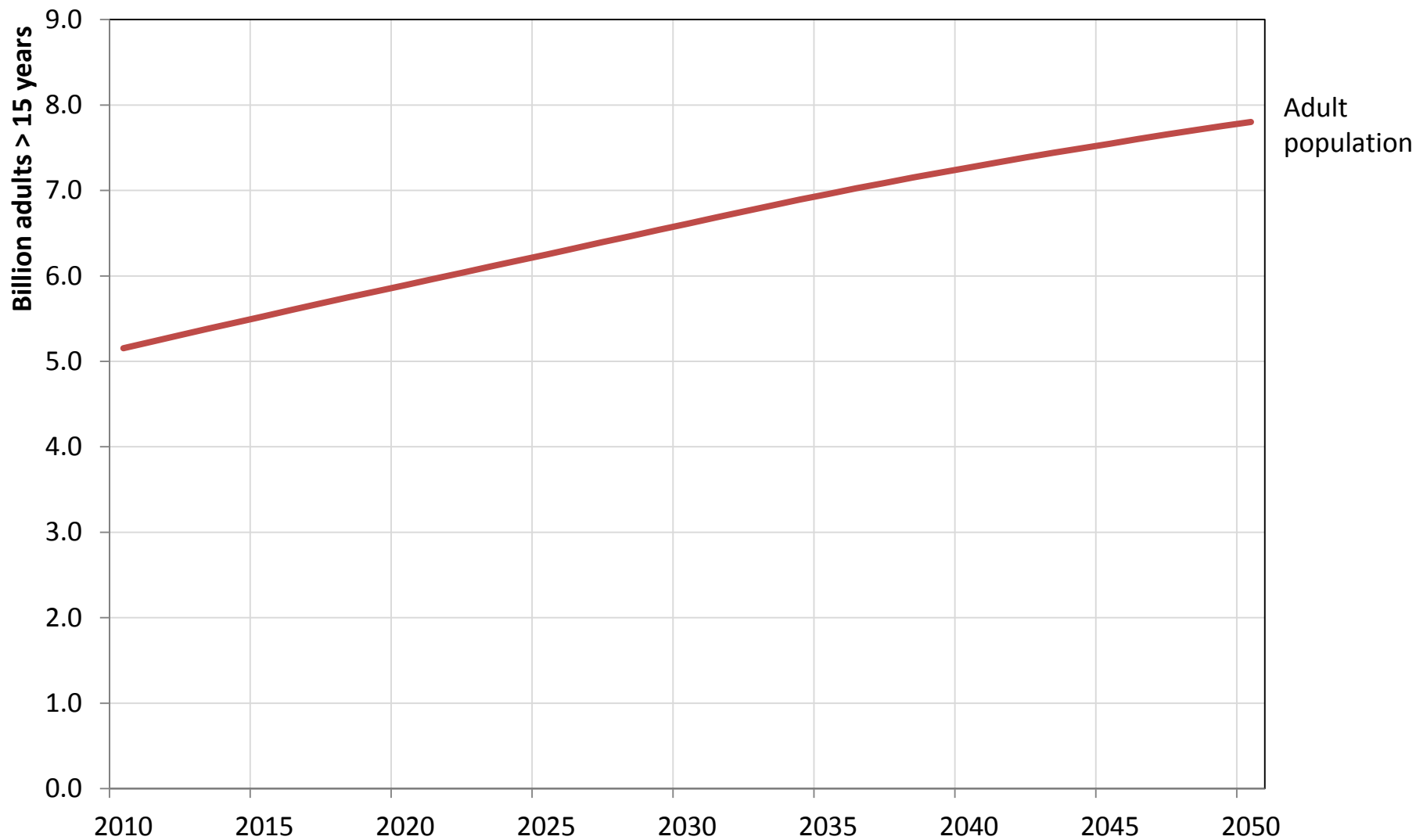
September 2011 I discovered e-cigarettes and they worked. It was like someone handed me a miracle. In less than a week I stopped using regular cigarettes. I haven't had a tobacco cigarette since.

From WHO Tobacco Atlas 2006 edition



The Endgame?

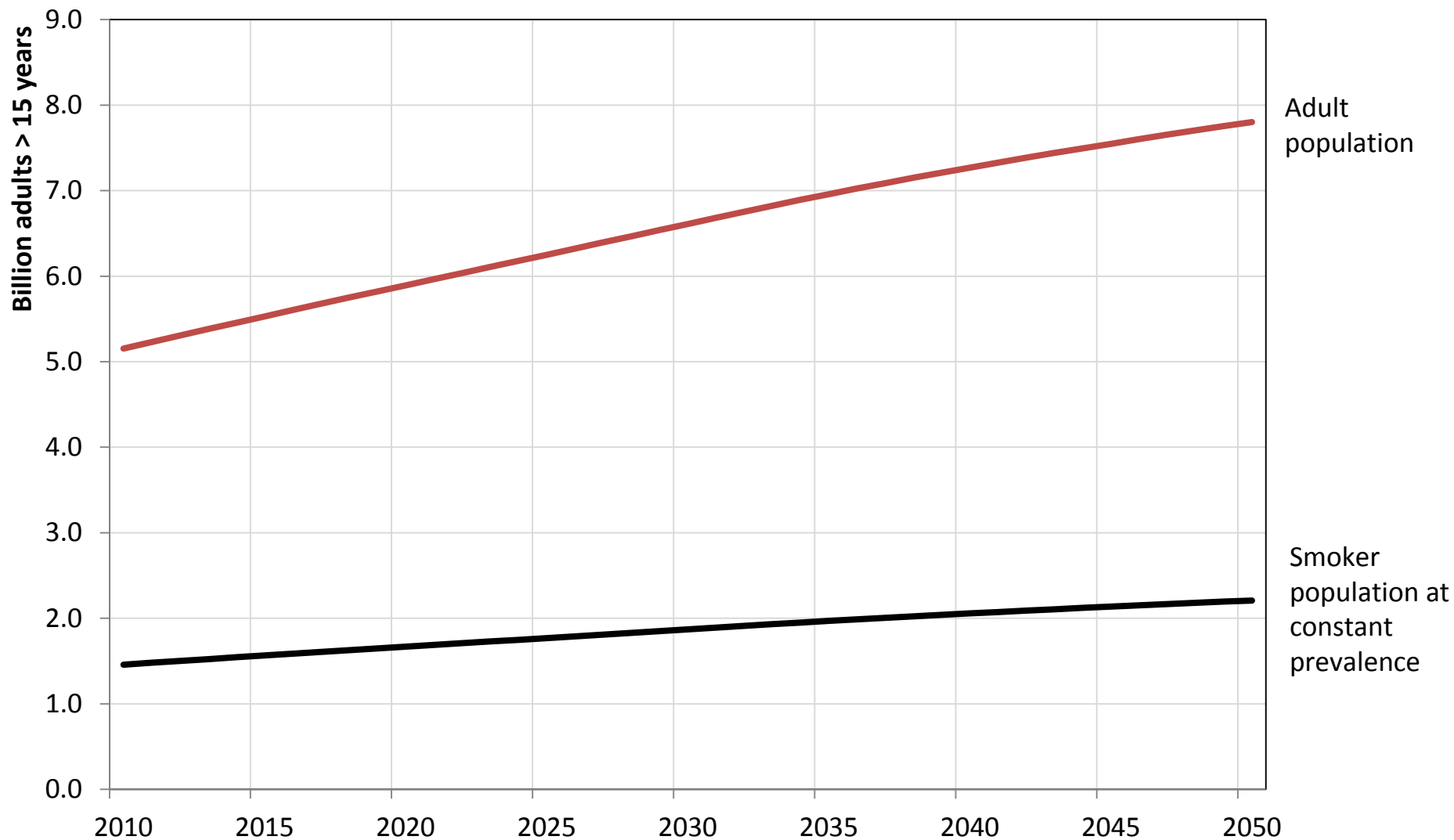
Projected global adult population growth



Smokers: WHO Tobacco Atlas 2006. Population: UN

The Endgame?

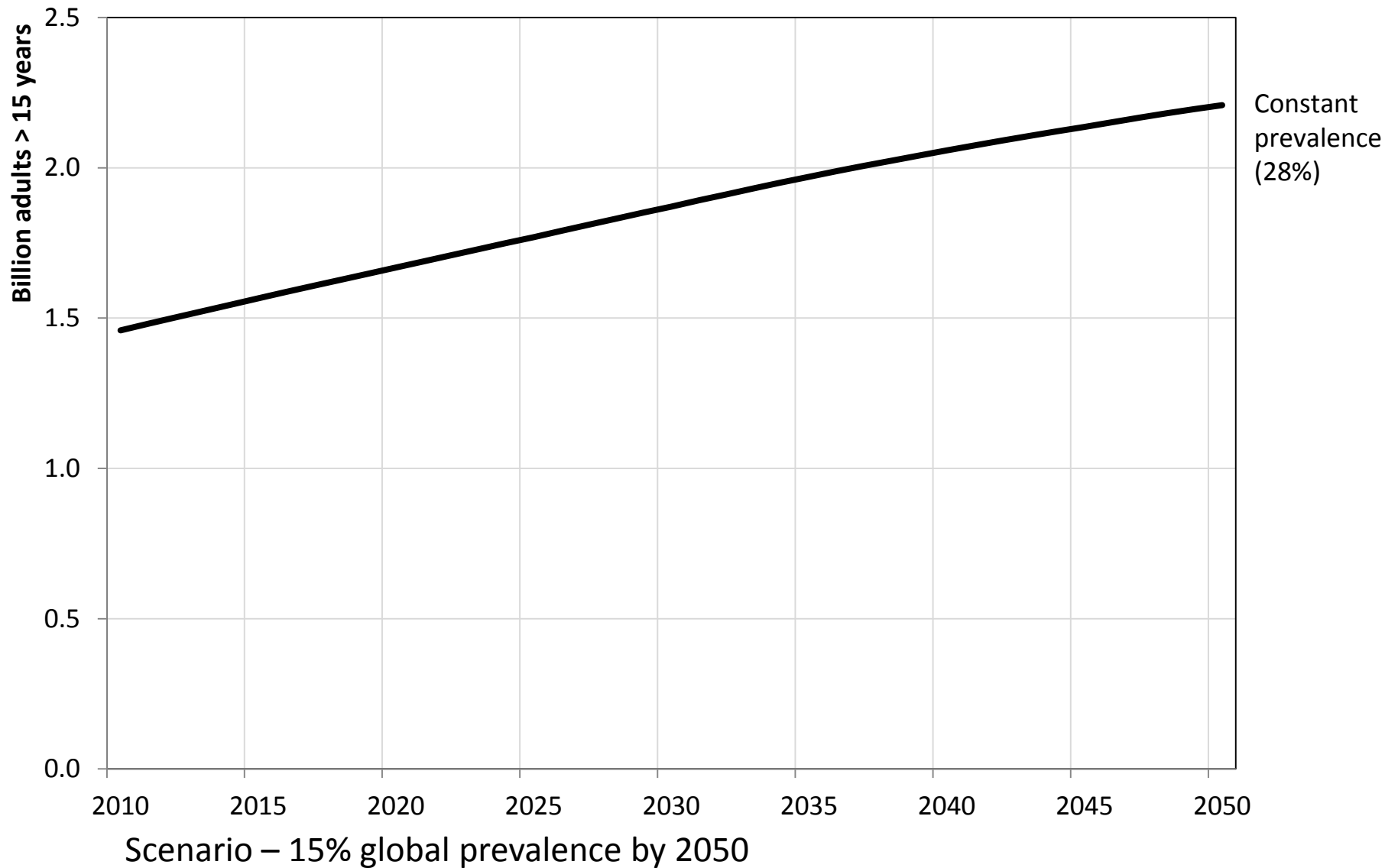
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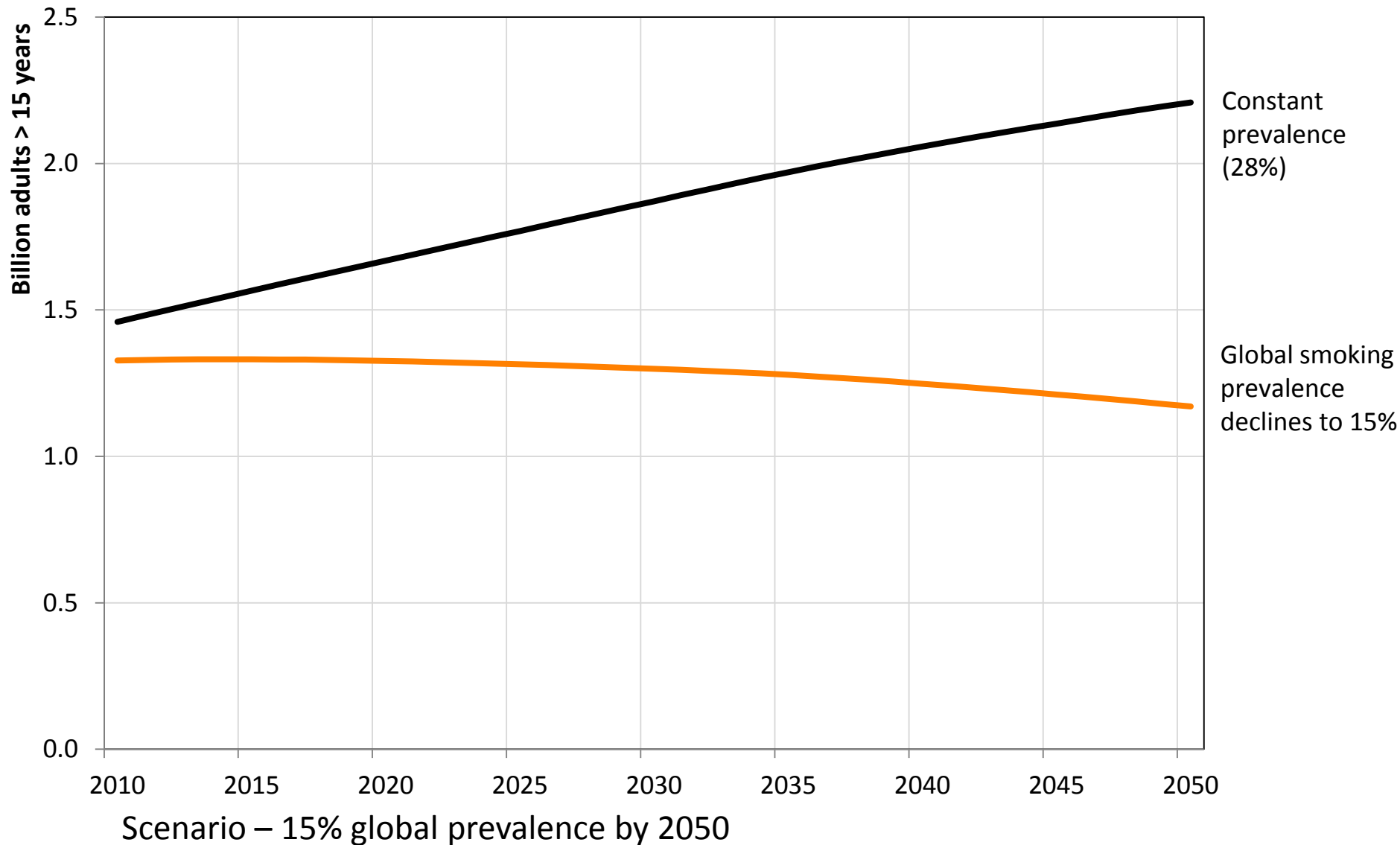
The endgame?

Scenarios for future smoker population



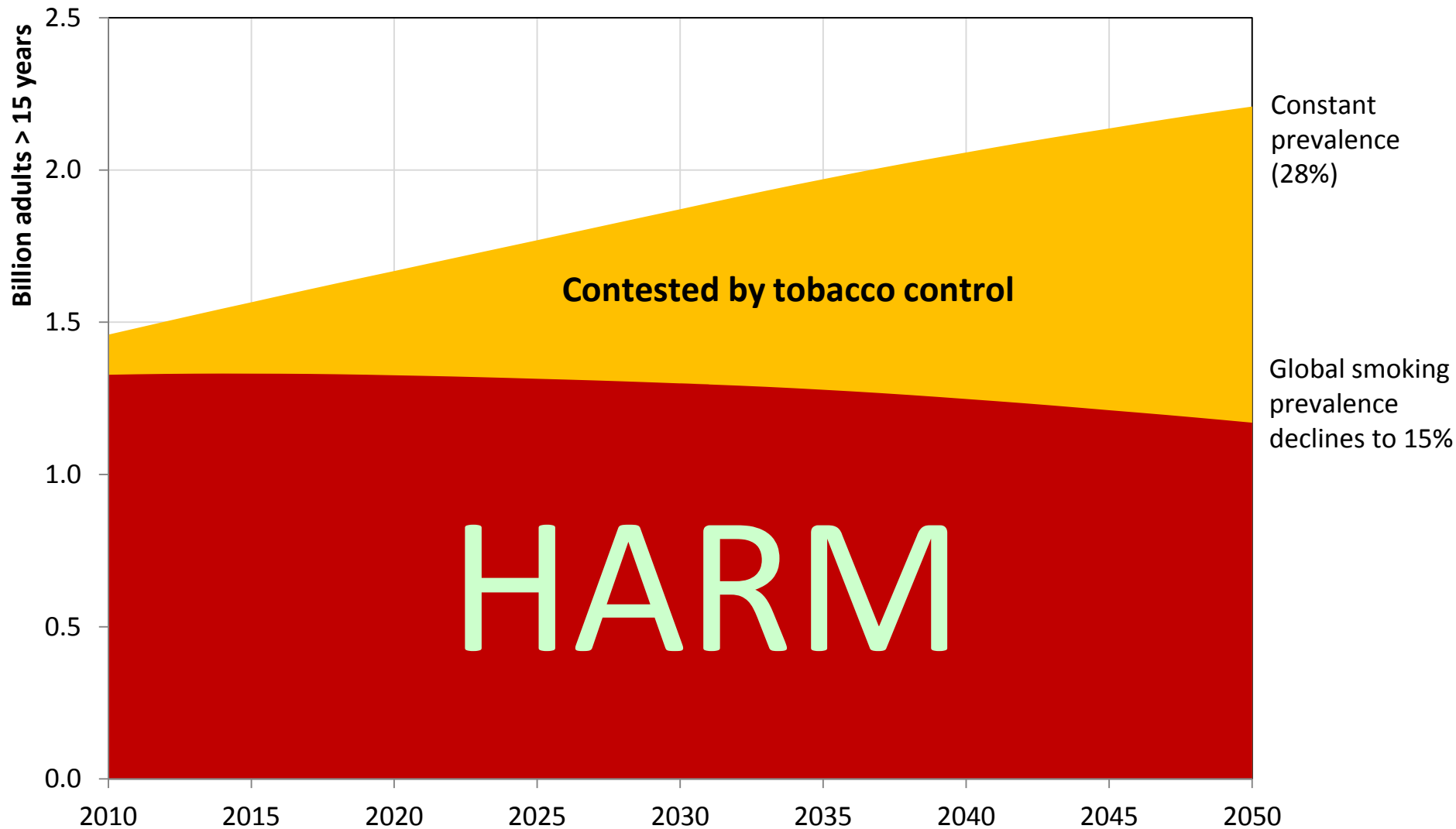
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Scenarios for future smoker population



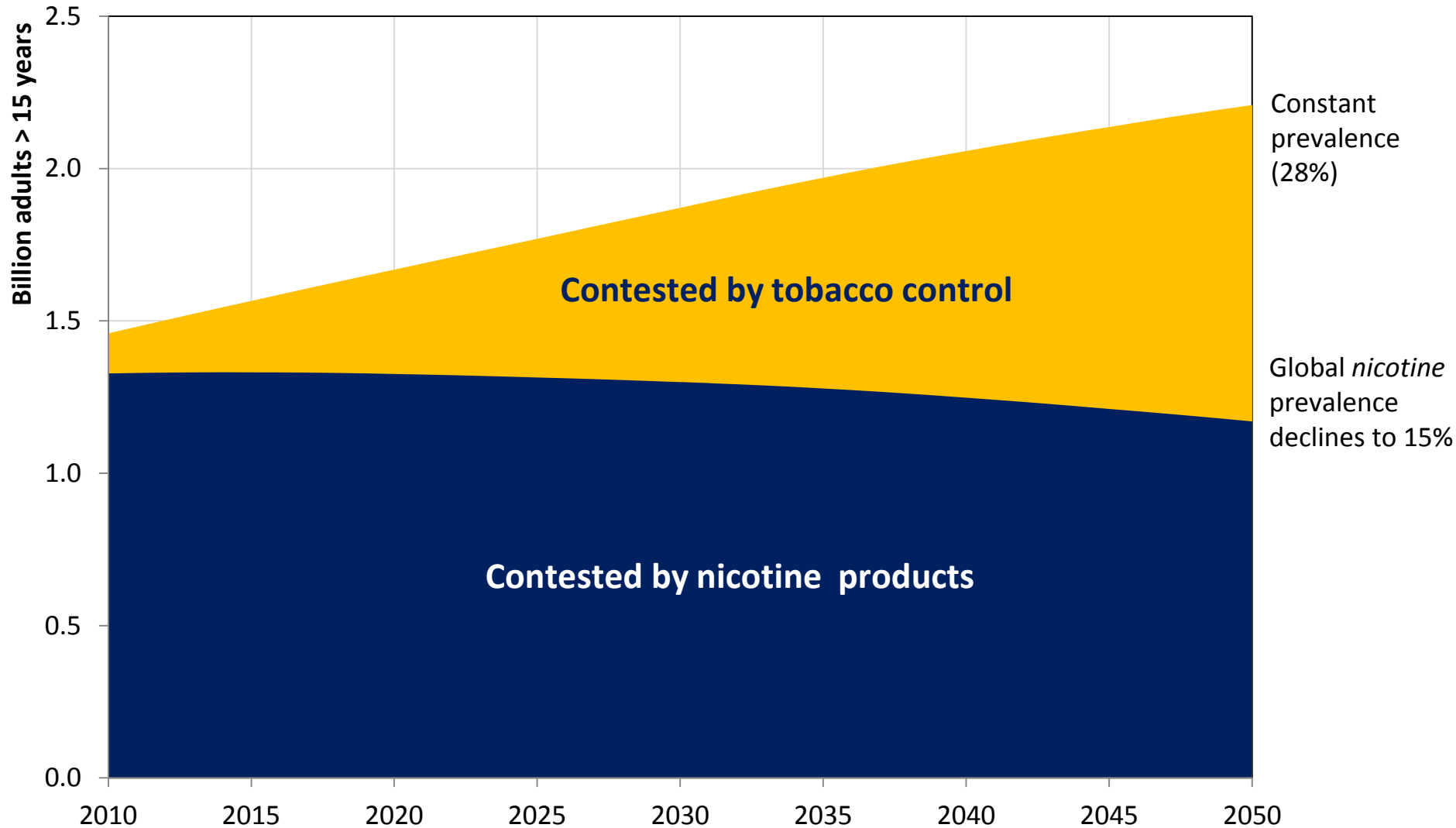
If all goes well

Scenarios for future smoker population



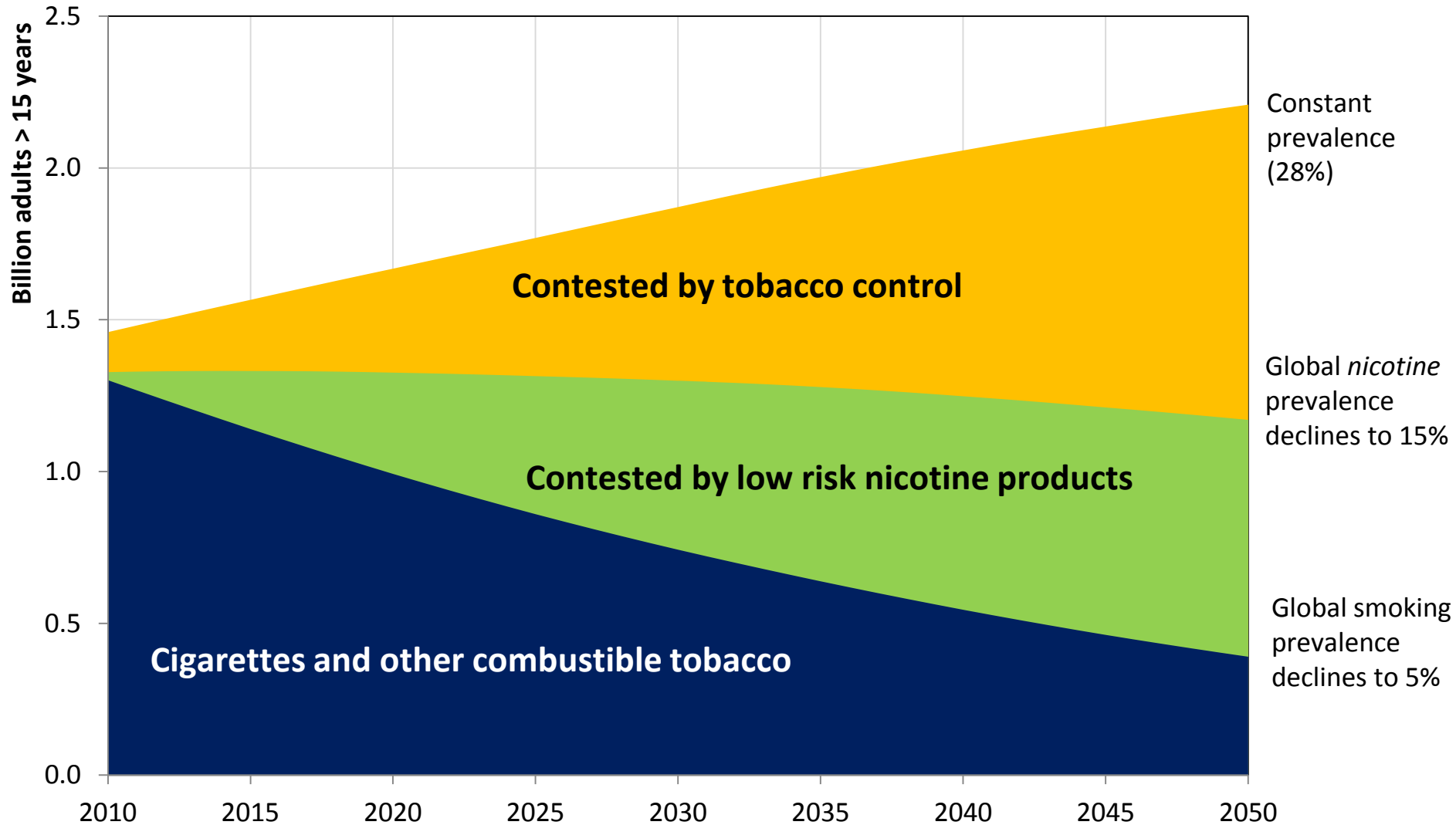
The endgame – a nicotine product contest?

Scenarios for future nicotine markets



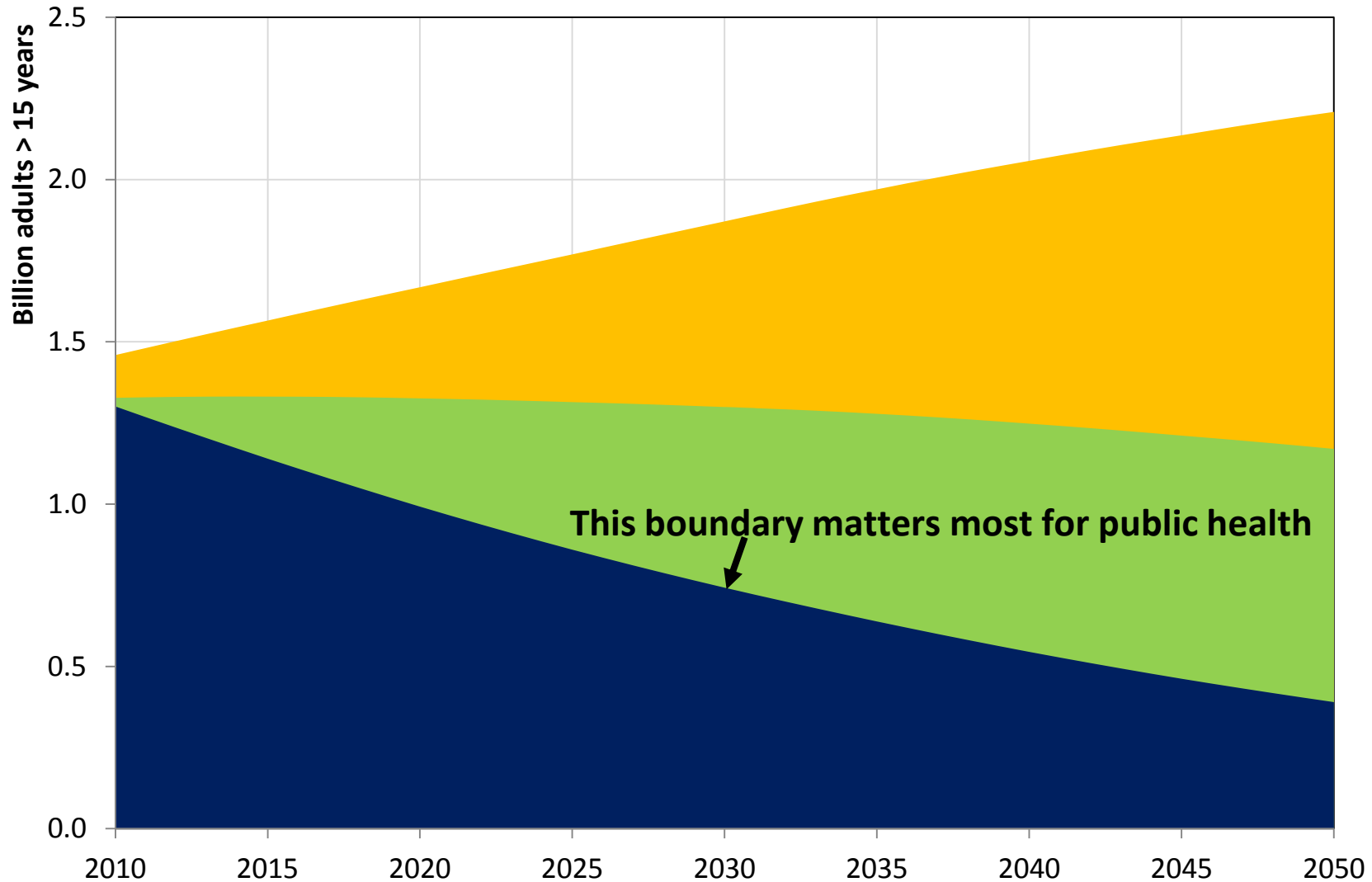
How far could low-risk nicotine products go?

Scenarios for future nicotine markets



How far could low-risk nicotine products go?

Scenarios for future nicotine markets



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

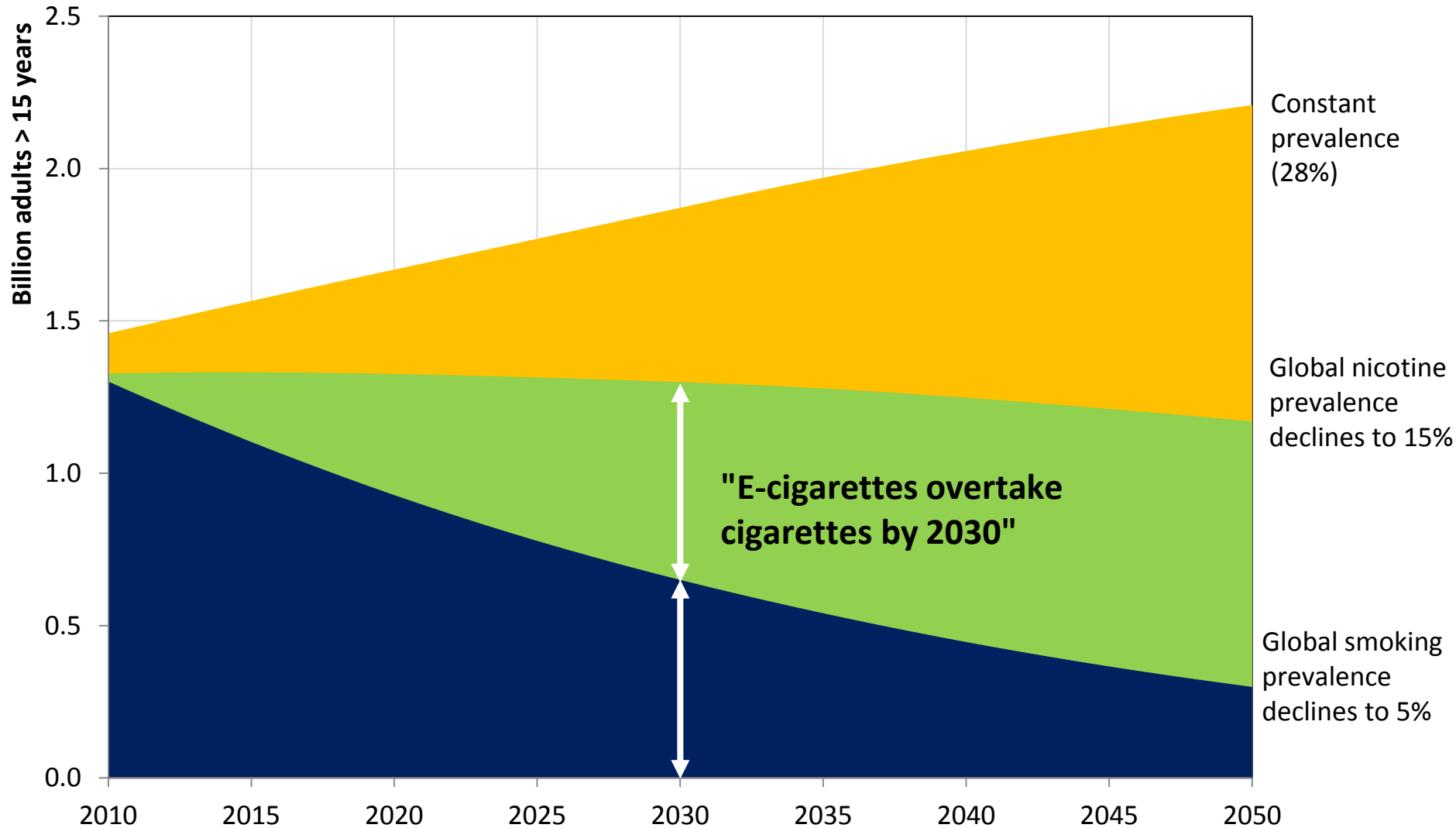
The endgame: analyst view

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50:50 by 2030

"Modified Herzog scenario" for future nicotine markets



Who is this?

Key messages

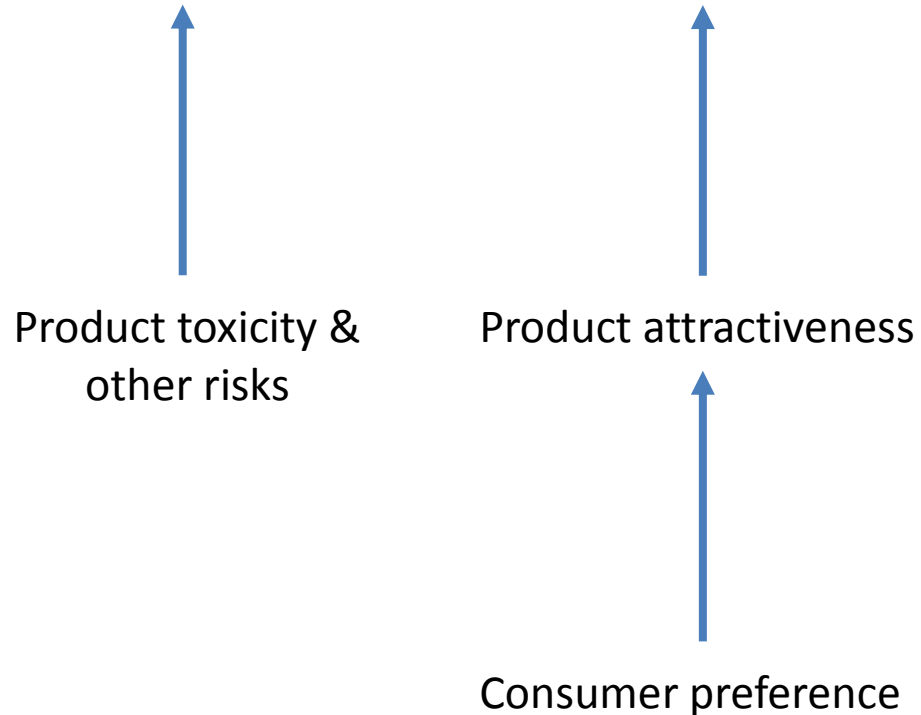
- Any evaluation of endgame strategies must start from the premise that there is a continuum of risk associated with nicotine-delivering products.
- Strategies should be pursued that encourage the use of the cleanest and safest form of nicotine delivery.
- Product regulation can play an important role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

Mitch Zeller

**(now) Director of the Center for Tobacco Products
FDA**

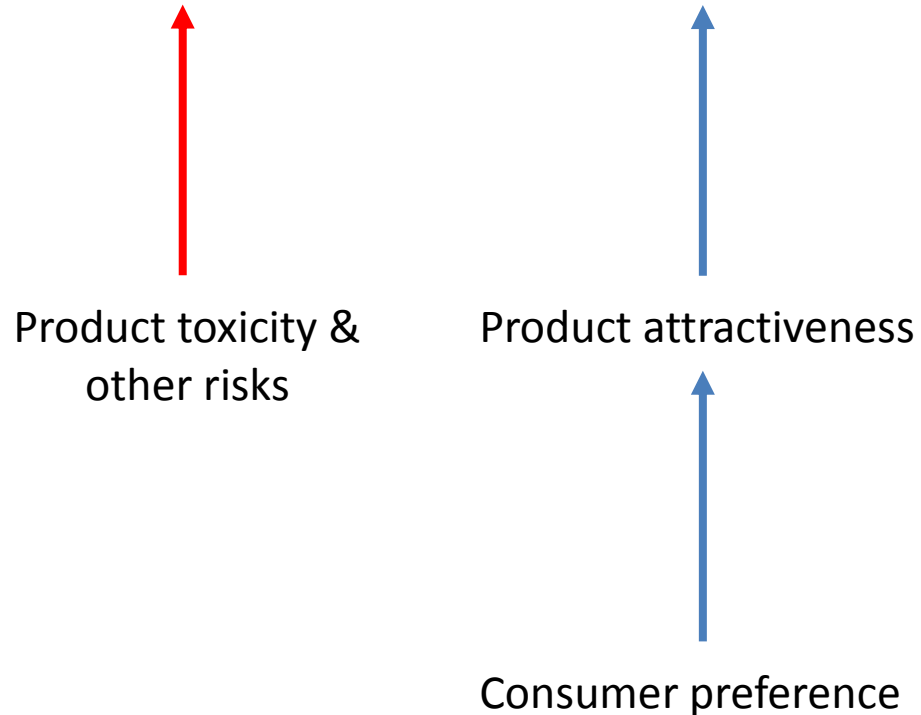
Harm reduction equation

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

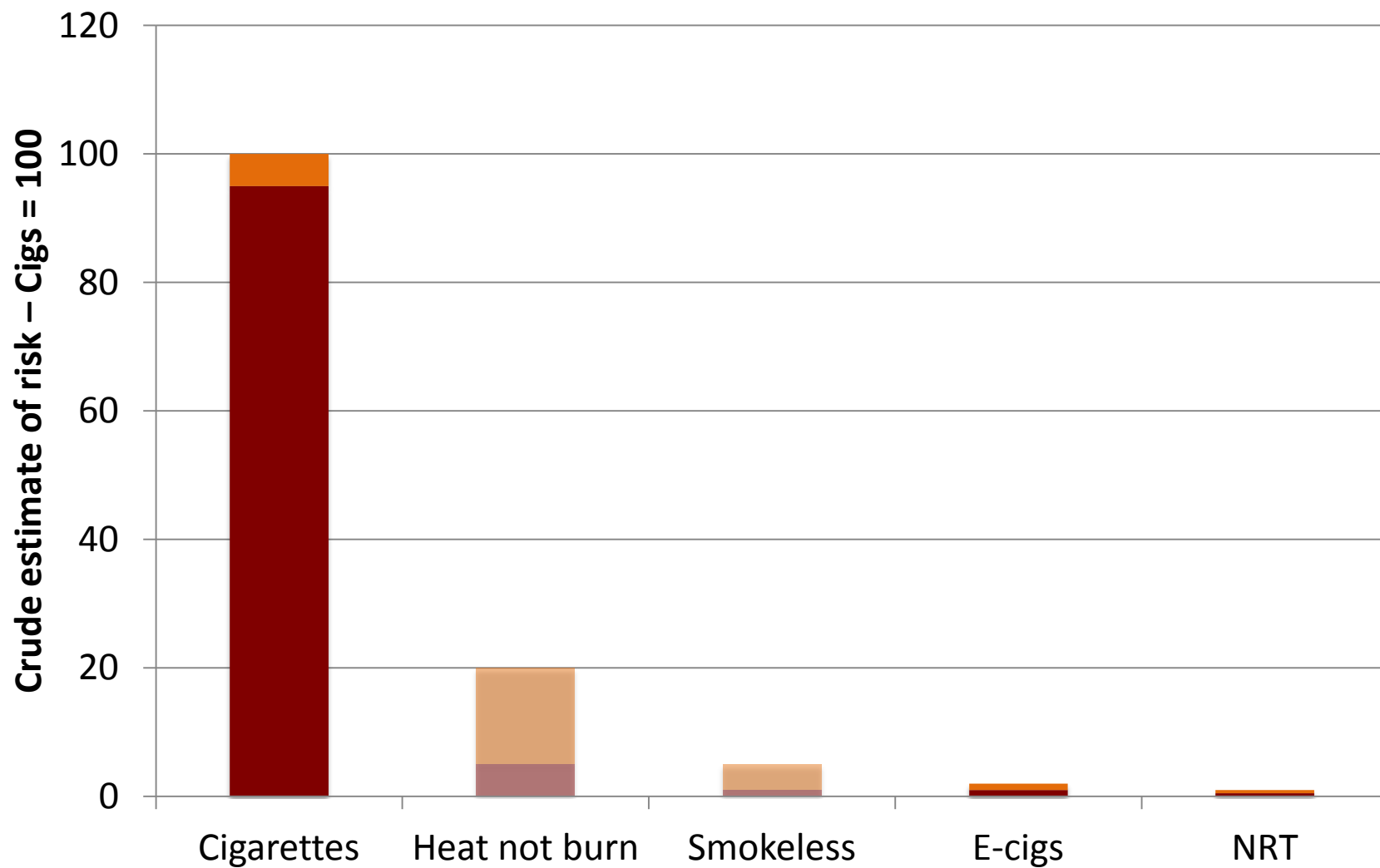


Harm reduction equation

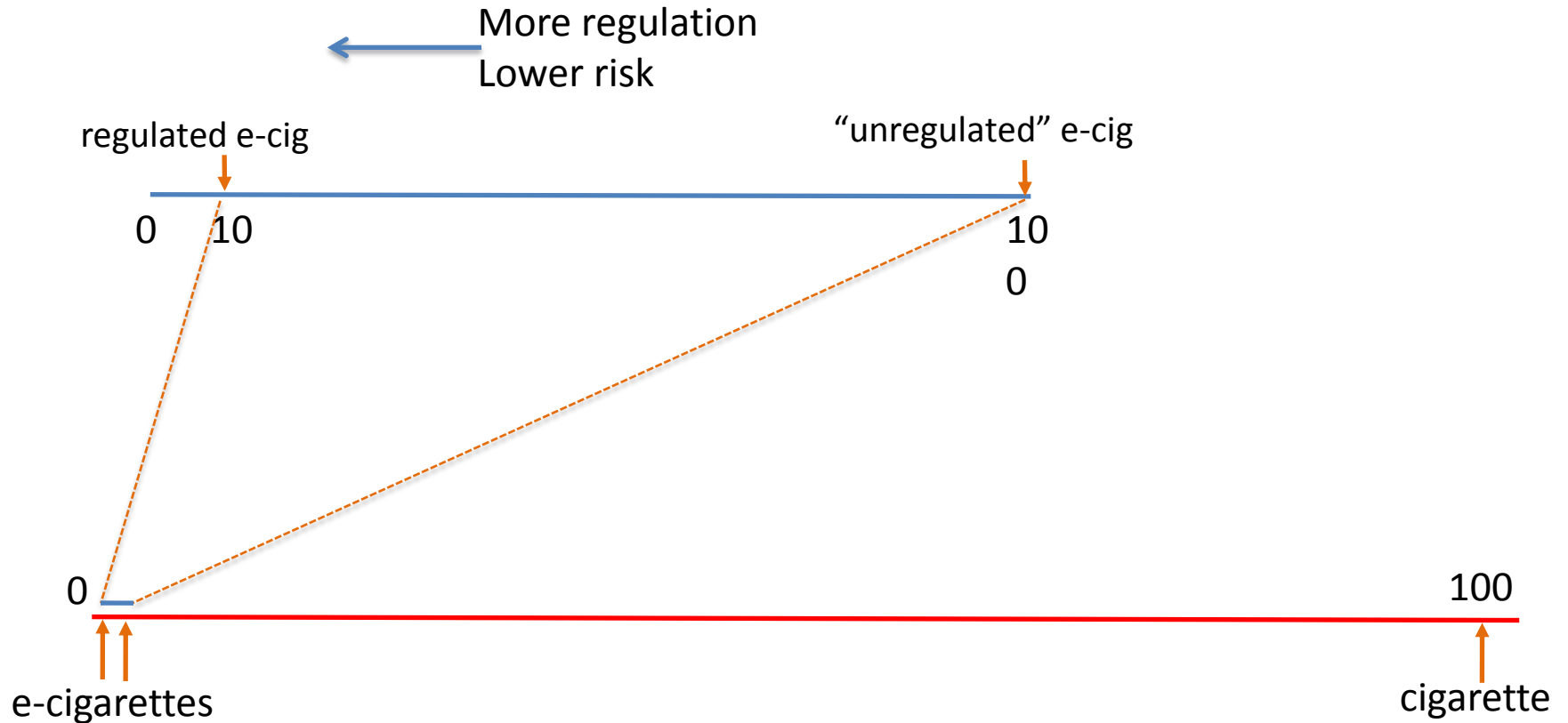
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Harm reduction categories – risk estimates

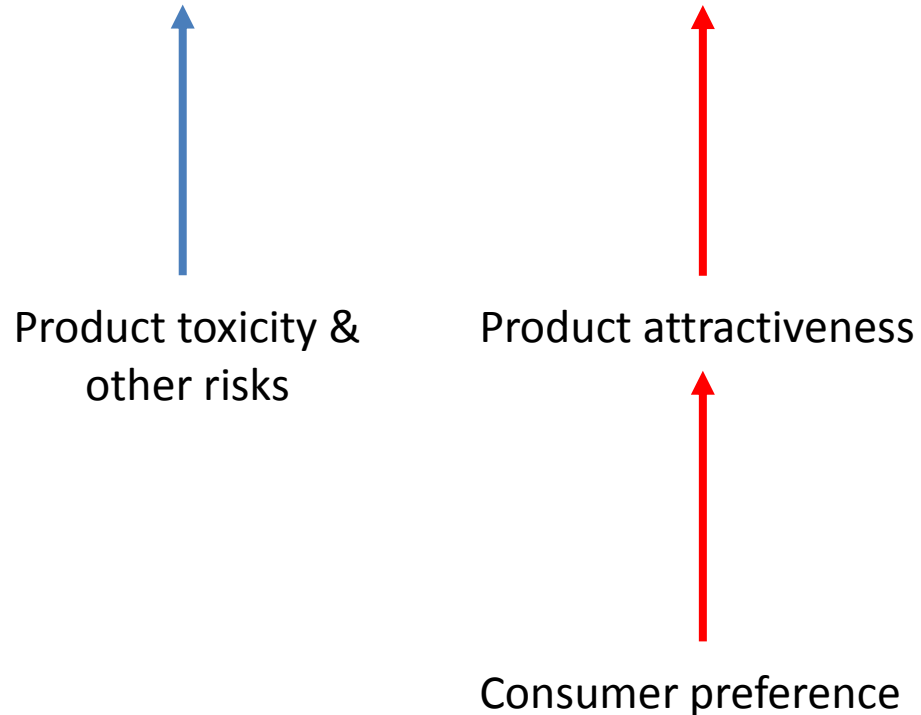


Focus on the right relative risk



Harm reduction equation

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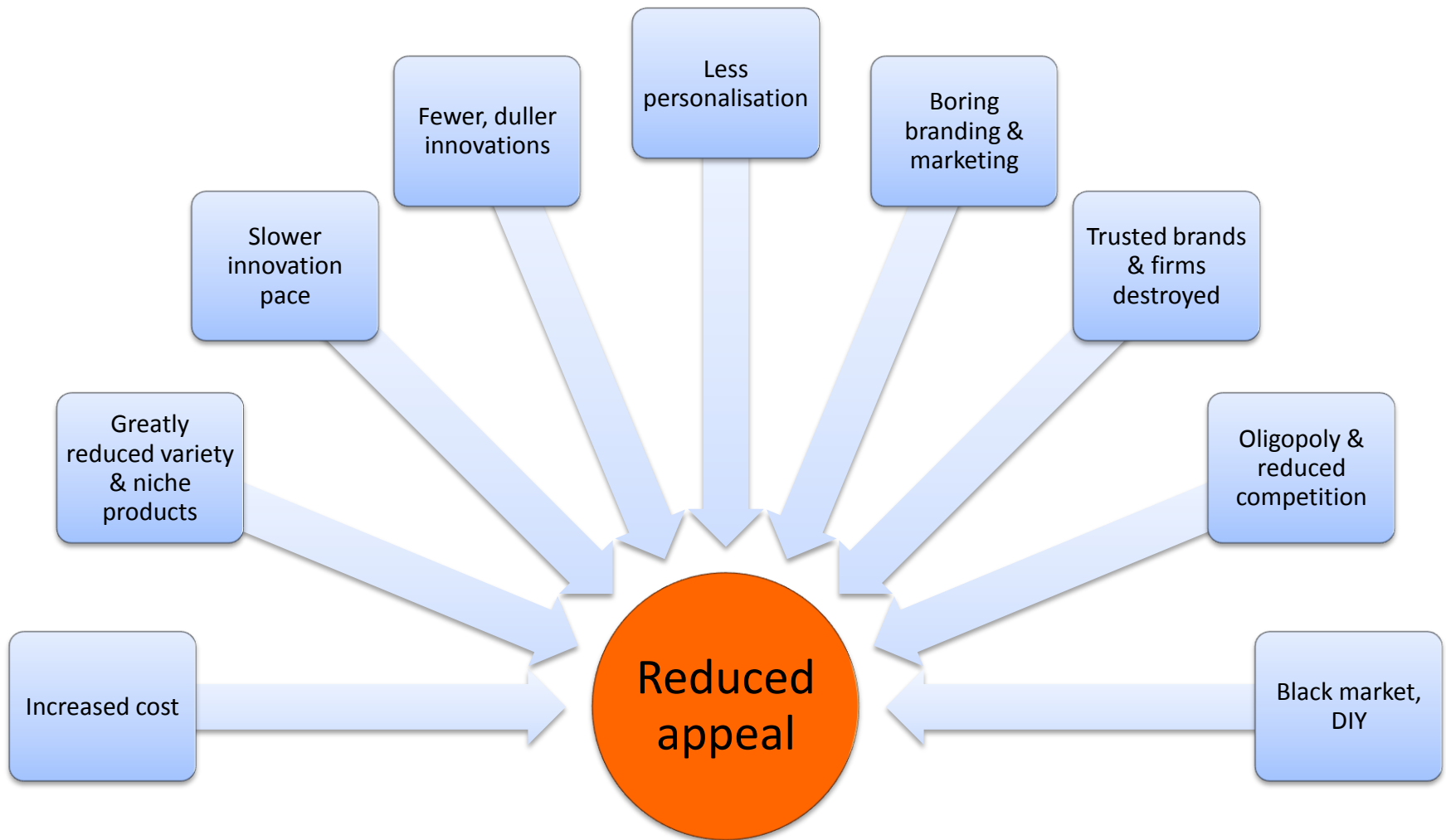


Analysts

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



Harm reduction equation

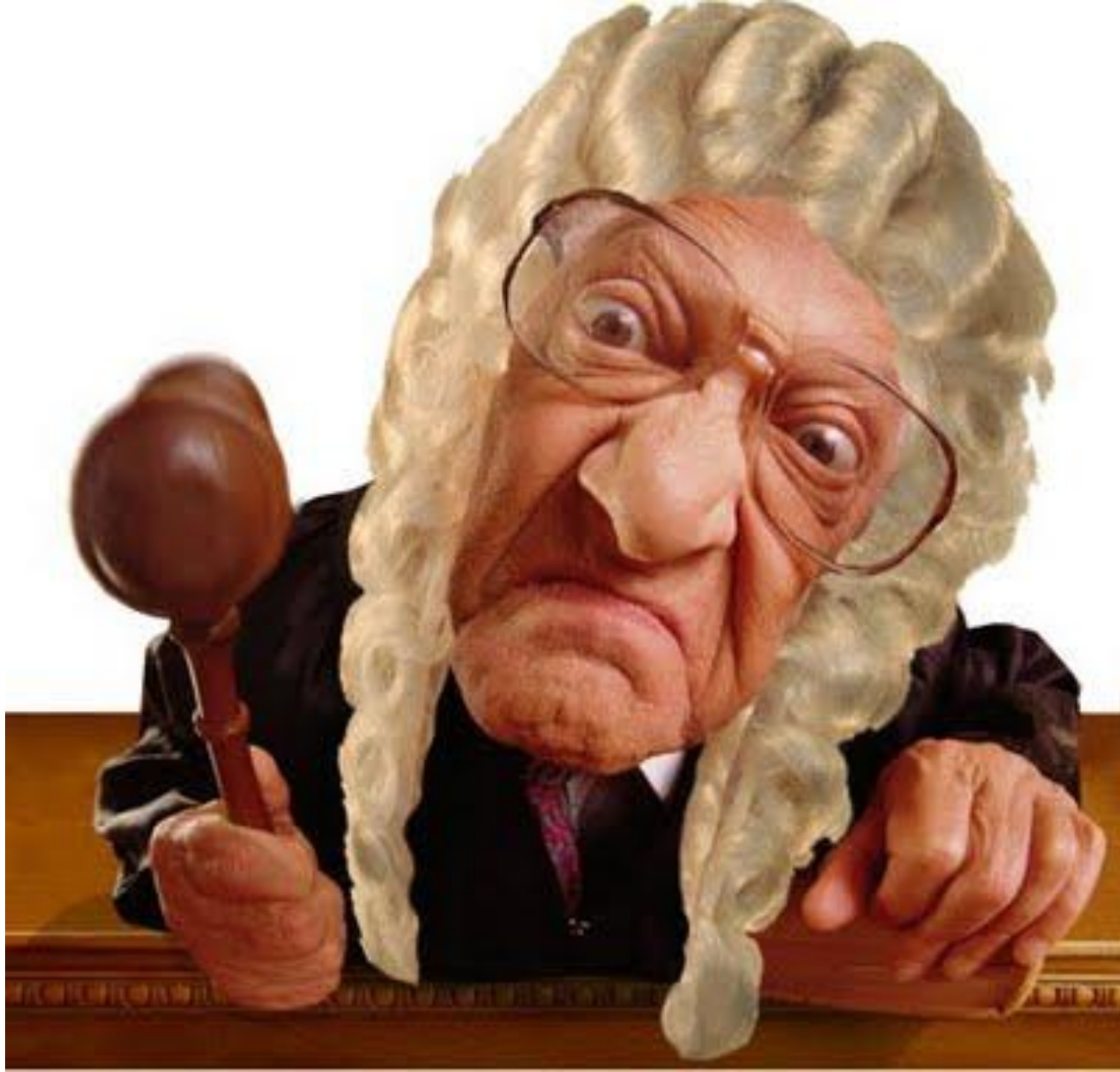
Harm reduction = Reduced risk x Number who switch



Trade offs

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

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

Quality

Treats or prevents disease

Efficacy

Adverse drug reactions

Safety



Getting tough on harm reduction?

	<u>Counter-productive</u>	<u>Harm reducing</u>
Safety	Safest possible	Safe enough
Quality	Control processes (eg. GMP)	Proportionate standards
Efficacy	Regulator decides	Consumer decides
Labelling	Warns of danger	Encourages switching
Marketing	Like medicines	Like consumer products
Bans on use	Fear of 'renormalisation'	Normalise harm reduction
Retail	Pharmacies / as tobacco	General sales
Age restrictions	Adults	Makes little real difference
Taxation	Like tobacco	Fiscal incentive to switch

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

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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

$$\text{Harm reduction} = \text{Reduced risk} \times \text{Number who switch} \\ - \text{Extra smokers} + \text{Extra quitters}$$



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

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