

Reduced Nicotine Rule

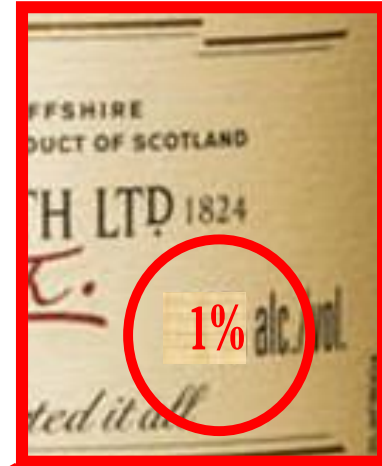
A terrible idea
(...to be pursued relentlessly)

Clive Bates
Counterfactual

FDLI meeting
26 October 2017
Washington DC

A terrible idea

1. A prohibition



A terrible idea

1. A prohibition
2. Unpredictable response

- Stockpile cigarettes or trade with stockpilers
- Import conventional cigarettes via internet
- Switch to other combustible products: hand rolling tobacco, pipes, cigars, hookahs, shisha
- Contraband or counterfeit conventional cigs
- Counterfeit low-nicotine with high nicotine
- Take advantage of product innovation
- Take advantage of process innovation
- Switch to ANDS – non-combustibles
- Add nicotine liquid to low-nicotine cigarettes
- Other substance use – e.g. marijuana
- Alternative risk behaviours
- Fraudulent solutions and quack remedies
- Some mixture of above – including dual use
- Quit smoking, tobacco and nicotine use
- Use very low nicotine cigarettes?

Really...?

A terrible idea

1. A prohibition
2. Unpredictable response
3. Little relevant research

Randomized Trial of Reduced-Nicotine Standards for Cigarettes

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ABSTRACT

BACKGROUND

The Food and Drug Administration can set standards that reduce the nicotine content of cigarettes.

METHODS

We conducted a double-blind, parallel, randomized clinical trial between June 2013 and July 2014 at 10 sites. Eligibility criteria included an age of 18 years or older, smoking of five or more cigarettes per day, and no current interest in quitting smoking. Participants were randomly assigned to smoke for 6 weeks either their usual brand of cigarettes or one of six types of investigational cigarettes, provided free. The investigational cigarettes had nicotine content ranging from 15.8 mg per gram of tobacco (typical of commercial brands) to 0.4 mg per gram. The primary outcome was the number of cigarettes smoked per day during week 6.

RESULTS

A total of 840 participants underwent randomization, and 780 completed the 6-week study. During week 6, the average number of cigarettes smoked per day was lower for participants randomly assigned to cigarettes containing 2.4, 1.3, or 0.4 mg of nicotine per gram of tobacco (16.5, 16.3, and 14.9 cigarettes, respectively) than for participants randomly assigned to their usual brand or to cigarettes containing 15.8 mg per gram (22.2 and 21.3 cigarettes, respectively; $P < 0.001$). Participants assigned to cigarettes with 5.2 mg per gram smoked an average of 20.8 cigarettes per day, which did not differ significantly from the average number among those who smoked control cigarettes. Cigarettes with lower nicotine content, as compared with control cigarettes, reduced exposure to and dependence on nicotine, as well as craving during abstinence from smoking, without significantly increasing the expired carbon monoxide level or total puff volume, suggesting minimal compensation. Adverse events were generally mild and similar among groups.

CONCLUSIONS

In this 6-week study, reduced-nicotine cigarettes versus standard-nicotine cigarettes reduced nicotine exposure and dependence and the number of cigarettes smoked. (Funded by the National Institute on Drug Abuse and the Food and Drug Administration Center for Tobacco Products; ClinicalTrials.gov number, NCT01681875.)

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N Engl J Med 2015;373:1340-9.
DOI: 10.1056/NEJMoa1502403
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3. Little relevant research
4. Perverse consequences



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4. Perverse consequences
5. Poor mandate

Limitation on Power Granted to the Food and Drug Administration

Because of the importance of a decision of the Secretary to issue a regulation

- A. banning all cigarettes, all smokeless tobacco products, all little cigars, all cigars other than little cigars, all pipe tobacco, or all roll-your-own tobacco products; or
- B. requiring the reduction of nicotine yields of a tobacco product to zero,

the Secretary is prohibited from taking such actions under this Act

U.S. Tobacco Control Act §907.d.3

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2. Unpredictable response
3. Little relevant research
4. Perverse consequences
5. Poor mandate
6. Brutal politics



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2. Unpredictable response
3. Little relevant research
4. Perverse consequences
5. Poor mandate
6. Brutal politics
7. Superior alternatives

Raise
taxes

Regulate
toxins

Control
additives

Plain
packaging

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7. Superior alternatives

To be pursued relentlessly

1. Alternatives essential



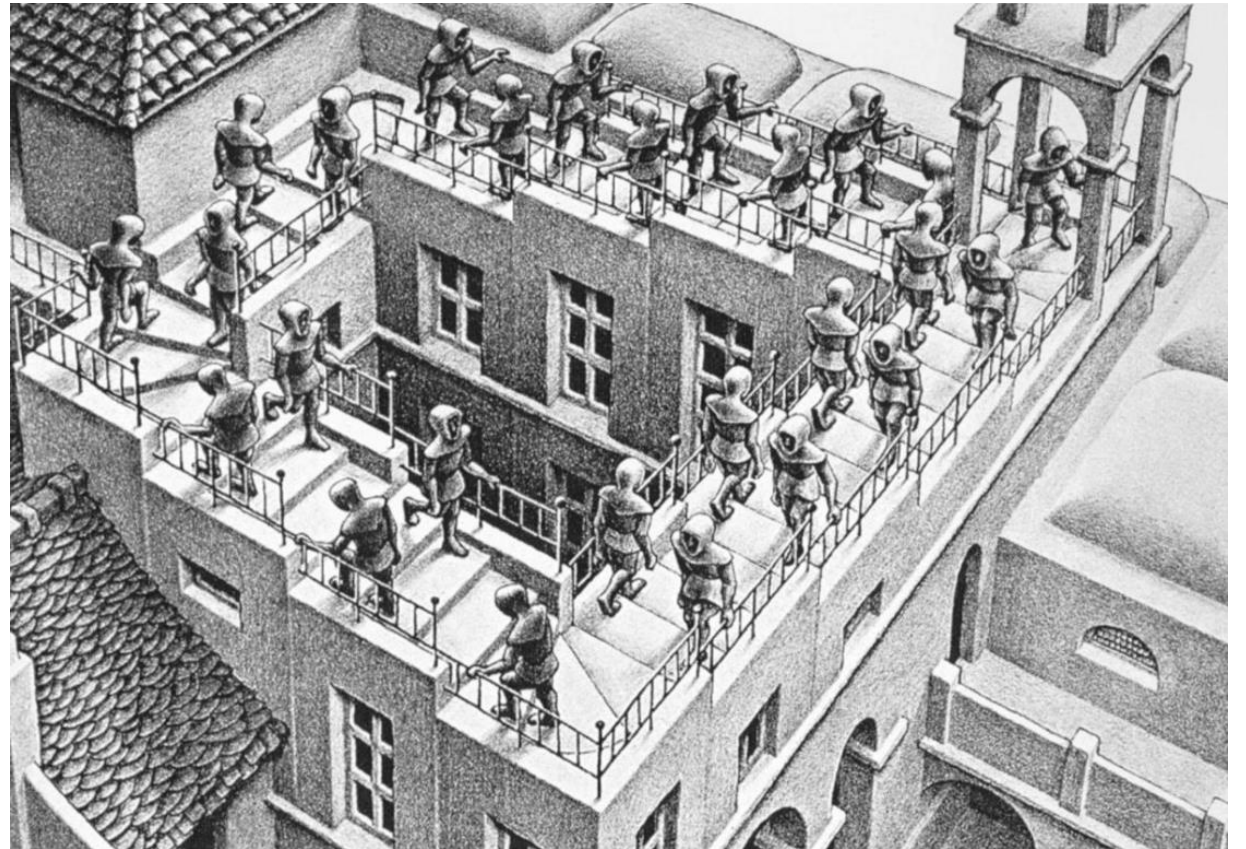
To be pursued relentlessly

1. Alternatives essential
2. Proportionate regulation



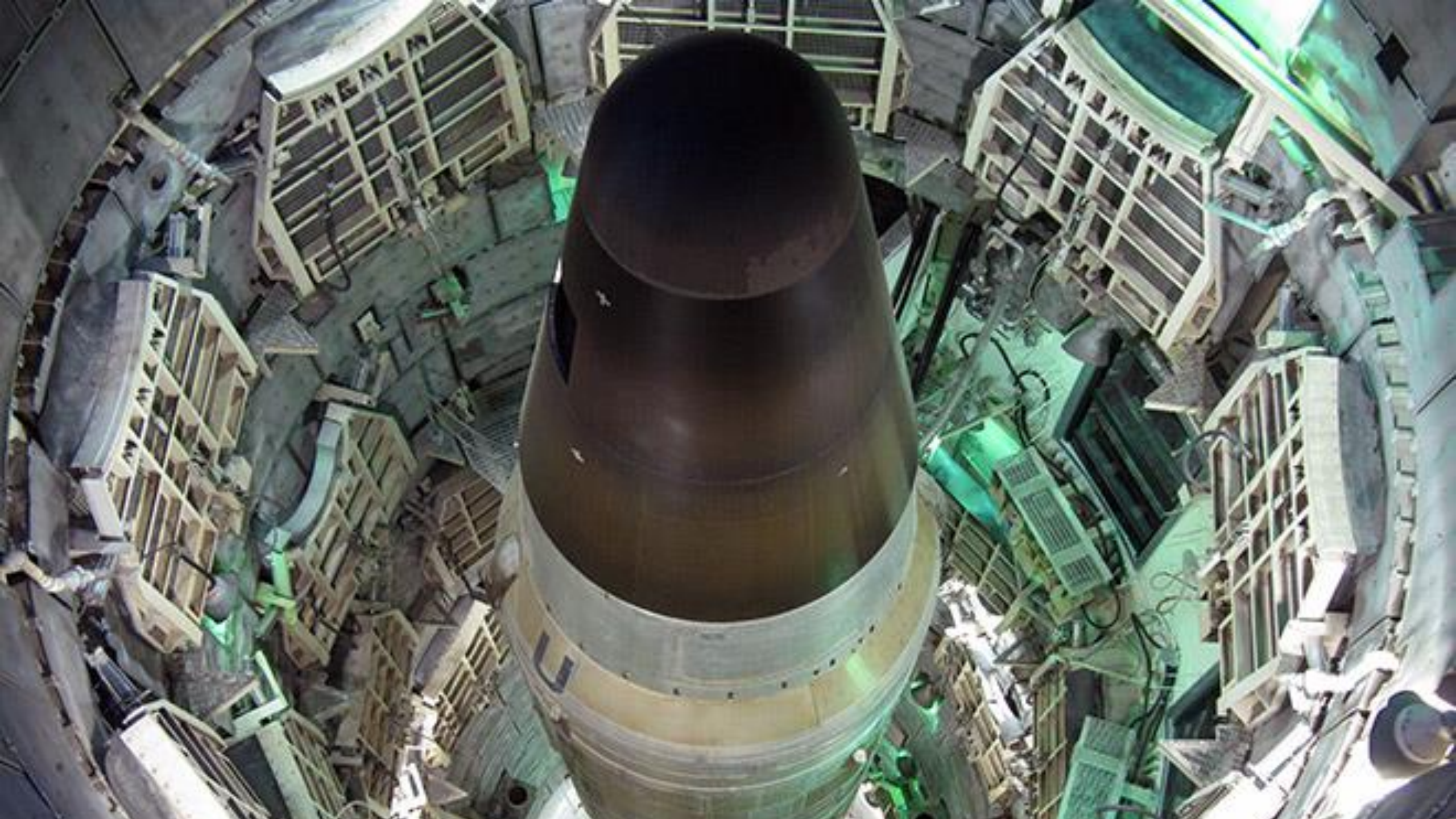
To be pursued relentlessly

1. Alternatives essential
2. Proportionate regulation
3. Coercion paradox



To be pursued relentlessly

1. Alternatives essential
2. Proportionate regulation
3. Coercion paradox
4. An 'agency threat'



Rules
Weapons don't have to be
used to be useful



Counterfactual

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