50 Years of Surgeon Generals’ Reports on Smoking and Health

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EPI/NPAM 2014
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50 years and only 25 minutes!!
BEFORE 1964
1950: Key Case-Control Studies

• Morton Levin publishes a study linking smoking and lung cancer in *JAMA*.
• Ernst L. Wynder and Evarts A. Graham publish a study in *JAMA* in which 96.5% of lung cancer patients interviewed were smokers.
• Richard Doll and Bradford Hill publish a study in *BMJ* finding that heavy smokers are 50 times more likely to get lung cancer; follow-up in 1954.

“...That so many diseases - major and minor - should be related to smoking is one of the most astonishing findings of medical research in this century; less astonishing perhaps than the fact that so many people have ignored it.”
1953-1954: The Evidence Mounts

Experimental Proponents

THE RELATIONSHIP BETWEEN YIELD AND TOBACCO CONSUMPTION

BRITISH MEDICAL JOURNAL
LONDON SATURDAY JUNE 26 1954

An analysis of information now available suggests that the over-all death rate, the death rate from cancer, and the death rate from heart disease among patients with other diseases. With one exception (the difference between the proportions of non-smokers found by McConnell, Gordon, and Jones) these differences are large enough to be important. While, therefore, the various authors have all shown

Hammond and Horn. JAMA 1954;155:1316-28

The questionary was intentionally kept short and simple in the hope of encouraging a high proportion of inquiry must have failed. were invited to give any habits or history which: from that, no in

Previous INVESTIGATION

one trial selected for use was the four p

1451-5


...
A Frank Statement to Cigarette Smokers

"We accept an interest in people's health as a basic responsibility, paramount to every other consideration in our business."

"We believe the products we make are not injurious to health."

"We always have and always will cooperate closely with those whose task it is to safeguard the public health."
Burney's two Statements

STATEMENT BY SURGEON GENERAL JEROY E BURNLEY

Excessive Cigarette Smoking

The Public Health Service is, of course, concerned with broad facts which substantially affect the health of the American people. The Service also has a responsibility to bring health facts to the attention of the health professions and the public.

In June 1956, units of the Public Health Service joined with two private voluntary health organizations to establish a scientific Study Group to appraise the available data on smoking and health. We have now reviewed the report of this Study Group and other recent data, including the report of Dr. W. C. Hammond and Dr. Daniel Heur to the American Medical Association in New York.

In the light of these studies, it is clear that there is an increasing and consistent body of evidence that excessive cigarette smoking is one of the causative factors of lung cancer.

The Study Group, appraising 18 independent studies, reported that lung cancer occurs much more frequently among cigarette smokers than among nonsmokers, and that a direct relationship between the incidence of lung cancer and the amount smoked. This finding was reinforced by the more recent report of Dr. Hammond and Dr. Heur.

Many independent studies that have confirmed beyond reasonable doubt that there is a high degree of statistical association between lung cancer and heavy and prolonged cigarette smoking.

Such evidence of a causal relationship is largely epidemiological in nature. It should be noted, however, that many important public health advances in the past have been due to one of the classic studies of statistical evidence. In the field of lung cancer, the Study Group noted that the evidence is increasingly pointing in one direction: that excessive smoking is one of the causative factors in lung cancer.

The evidence weighs in the favor of the hypothesis that dangerous smoking is due to one of the causative factors in bronchogenic carcinoma. This evidence is not conclusive, but it is consistent with the hypothesis that the smoking habit is a causative factor in lung cancer.

The Study Group also noted that the habit of smoking is not causative in the bronchogenic carcinoma of lung cancer, which is the subject of public health interest.

In 1957, the Surgeon General recommended that all health professionals and the public be apprised of the evidence that excessive cigarette smoking is a causative factor in lung cancer.

PUBLIC HEALTH REPORTS

Volume 72, No. 3

SPECIAL ARTICLE

SPECIAL ARTICLE

SMOKING AND LUNG CANCER

A STATEMENT OF THE PUBLIC HEALTH SERVICE

Lever, E. Burnley, M.D., Washington, D.C.

Lever and Belknap: "The latest paper in the Massachusetts studies on lung cancer and smoking deserves particular mention. The document of each case is unusually thorough, covering a wide range of factors. An extensive series of controls was subjected to the same scrutiny. In a series of patients known to have died of lung cancer, four variables showed significant correlation and association: frequent or chronic respiratory conditions, heavy cigarette smoking, heavy consumption of alcohol, and outdoor work. Of these four variables, heavy cigarette smoking had the strongest relationship to lung cancer. About 90 percent of the persons with lung cancer were heavy cigarette smokers (more than 100 cigars)."

However, there was still an important role for controlling smoking as a way to prevent future cases of lung cancer.

Burney's two Statements

Source: Public Health Rep. 1957 September

Source: JAMA. 1959 November
1964
Adult per-capita cigarette consumption and major smoking and health events, US, 1900-2012

- 1964 Surgeon General’s report on smoking and health
- Reassurance campaign begins
- Broadcast ad ban
- Nonsmokers’ rights movement begins
- Federal cigarette tax doubles
- Press doctrine messages on broadcast media
- 1986 Surgeon General’s report on secondhand smoke
- Cigarette price drop
- FDA General’s report on secondhand smoke (an update)
- Federal $1.01 tax increase
- Synar Amendment enacted
- Nicotine medications available over-the-counter
- Master Settlement Agreement
- Family Smoking Prevention and Tobacco Control Act

Number of cigarettes

Year

Surgeon General’s Committee on Smoking and Health 1963

"Three of the members smoked cigarettes, and two others smoked pipes or cigars. Terry, himself a smoker, served as the nominal Chairman of the group, but it was agreed that he would not participate in any of its deliberations or conclusions."
Statement on Methods

• “A plan was adopted at the first meeting…”
• “…a major general requirement was that of making the information available…”
• “…made decisions or judgments at three levels…”: 1) validity of a publication or report; 2) validity of interpretations and conclusions of authors; and 3) conclusions of the committee.
• Criteria for causal inference
Causal Criteria

Statistical methods cannot establish proof of a causal relationship in an association. The causal significance of an association is a matter of judgment which goes beyond any statement of statistical probability. To judge or evaluate the causal significance of the association between the attribute or agent and the disease, or effect upon health, a number of criteria must be utilized, no one of which is an all-sufficient basis for judgment. These criteria include:

a) The consistency of the association
b) The strength of the association
c) The specificity of the association
d) The temporal relationship of the association
e) The coherence of the association
# Smoking and Mortality, 1964

## Table 2. Expected and observed deaths for smokers of cigarettes only and mortality ratios in seven prospective studies

<table>
<thead>
<tr>
<th>Underlying cause of death</th>
<th>Expected deaths</th>
<th>Observed deaths</th>
<th>Mortality ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer of lung (162-3)</td>
<td>170.3</td>
<td>1,833</td>
<td>10.8</td>
</tr>
<tr>
<td>Bronchitis and emphysema (502, 521.1)</td>
<td>89.5</td>
<td>546</td>
<td>6.1</td>
</tr>
<tr>
<td>Cancer of larynx (161)</td>
<td>14.0</td>
<td>75</td>
<td>5.4</td>
</tr>
<tr>
<td>Oral cancer (140-8)</td>
<td>37.0</td>
<td>152</td>
<td>4.1</td>
</tr>
<tr>
<td>Cancer of esophagus (150)</td>
<td>33.7</td>
<td>113</td>
<td>3.4</td>
</tr>
<tr>
<td>Stomach and duodenal ulcers (540, 541)</td>
<td>195.1</td>
<td>294</td>
<td>2.8</td>
</tr>
<tr>
<td>Other circulatory diseases (451-68)</td>
<td>254.0</td>
<td>649</td>
<td>2.6</td>
</tr>
<tr>
<td>Cirrhosis of liver (581)</td>
<td>169.2</td>
<td>379</td>
<td>2.2</td>
</tr>
<tr>
<td>Cancer of bladder (181)</td>
<td>111.6</td>
<td>216</td>
<td>1.9</td>
</tr>
<tr>
<td>Coronary artery disease (420)</td>
<td>6,430.7</td>
<td>11,177</td>
<td>1.7</td>
</tr>
<tr>
<td>Other heart diseases (421-2, 430-4)</td>
<td>526.0</td>
<td>868</td>
<td>1.7</td>
</tr>
<tr>
<td>Hypertensive heart (440-3)</td>
<td>409.2</td>
<td>631</td>
<td>1.5</td>
</tr>
<tr>
<td>General arteriosclerosis (450)</td>
<td>210.7</td>
<td>310</td>
<td>1.5</td>
</tr>
<tr>
<td>Cancer of kidney (180)</td>
<td>79.0</td>
<td>120</td>
<td>1.5</td>
</tr>
<tr>
<td>All causes</td>
<td>15,653.9</td>
<td>23,223</td>
<td>1.68</td>
</tr>
</tbody>
</table>

1 Abridged from Table 25, Chapter 8. Mortality.
2 International Statistical Classification numbers in parentheses.
3 Includes all other causes of death as well as those listed above.

Source: USDHEW 1964
Smoking and Mortality, reconstructed in 2014

A  Death from Any Cause

<table>
<thead>
<tr>
<th>Study</th>
<th>Weight (fixed)</th>
<th>Weight (random)</th>
<th>Incidence Rate Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>British Doctors</td>
<td>7.5</td>
<td>14.8</td>
<td>1.44 (1.32–1.56)</td>
</tr>
<tr>
<td>Men in 9 States</td>
<td>19.6</td>
<td>18.5</td>
<td>1.70 (1.61–1.79)</td>
</tr>
<tr>
<td>U.S. Veterans</td>
<td>40.2</td>
<td>20.1</td>
<td>1.79 (1.73–1.86)</td>
</tr>
<tr>
<td>California Occupational</td>
<td>1.0</td>
<td>4.6</td>
<td>1.78 (1.41–2.25)</td>
</tr>
<tr>
<td>California Legion</td>
<td>1.6</td>
<td>6.6</td>
<td>1.58 (1.32–1.90)</td>
</tr>
<tr>
<td>Canadian Veterans</td>
<td>14.6</td>
<td>17.6</td>
<td>1.65 (1.56–1.76)</td>
</tr>
<tr>
<td>Men in 25 States</td>
<td>15.6</td>
<td>17.8</td>
<td>1.63 (1.54–1.73)</td>
</tr>
<tr>
<td>Fixed-effects model</td>
<td>100.0</td>
<td>—</td>
<td>1.69 (1.66–1.73)</td>
</tr>
<tr>
<td>Random-effects model</td>
<td>—</td>
<td>100.0</td>
<td>1.65 (1.56–1.75)</td>
</tr>
</tbody>
</table>

Source: Schumacher et al. NEJM 2014;370(2):186-8
The Committee’s judgment in brief:
Cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action.

- Cigarette smoking is **causally related to lung cancer in men**; the magnitude of the effect of cigarette smoking far outweighs all other factors. The data for women, though less extensive, point in the same direction.
- Cigarette smoking is the most important of the causes of **chronic bronchitis** in the United States, and increases the risk of dying from chronic bronchitis.
- Male cigarette smokers have a **higher death rate from coronary artery disease** than non-smoking males, but it is not clear that the association has causal significance.
- Cigarette smoking is associated with a 70 percent increase in the age-specific death rates of males, and to a lesser extent with increased death rates of females. The total number of excess deaths causally related to cigarette smoking in the U.S. population cannot be accurately estimated. In view of the continuing and mounting evidence from many sources, it is the judgment of the Committee that **cigarette smoking contributes substantially to mortality from certain specific diseases and to the overall death rate**.
KEY REPORTS SINCE 1964
Adult per-capita cigarette consumption and major smoking and health events, US, 1900-2012

- U.S. entry into WWI
- Great Depression begins
- 1964 Surgeon General's report on smoking and health
- Broadcast ad ban
- Nonsmokers' rights movement begins
- Federal cigarette tax doubles
- 1986 Surgeon General's report on secondhand smoke
- USSA Amendment enacted
- Nicotine medications available over-the-counter
- Master Settlement Agreement
- Family Smoking Prevention and Tobacco Control Act
- Cigarette price drop
- FDA proposed rule
- 2006 Surgeon General's report on secondhand smoke (an update)
- Federal $1.01 tax increase
Adult per-capita cigarette consumption and major smoking and health events, US, 1900-2012

- 1900: U.S. entry into WWI
- 1929: Great Depression begins
- 1939: U.S. entry into WWII
- 1954: Reassurance campaign begins
- 1964: Surgeon General's report on smoking and health
- 1979: Broadcast ad ban
- 1986: Surgeon General's report on secondhand smoke
- 1996: Nonsmokers' rights movement begins
- 2006: Surgeon General's report on secondhand smoke (an update)

Key events:
- Synar Amendment enacted
- Nicotine medications available over-the-counter
- Master Settlement Agreement
- Family Smoking Prevention and Tobacco Control Act
- Cigarette price drop
- FDA proposed rule
- Federal $1.01 tax increase
Adult per-capita cigarette consumption and major smoking and health events, US, 1900-2012

- 1964 Surgeon General's report on smoking and health
- Broadcast ad ban
- Reassurance campaign begins
- Nonsmokers' rights
- 1986 Surgeon General's report on secondhand smoke
- 1986 Surgeon General's report on secondhand smoke (an update)
- Synar Amendment enacted
- Nicotine medications available over-the-counter
- Master Settlement Agreement
- Family Smoking Prevention and Tobacco Control Act
- Cigarette price drop
- FDA proposed rule
- 2006 Surgeon General's report on secondhand smoke (an update)
- Federal $1.01 tax increase

Key Events:
- U.S. entry into WWI
- Great Depression begins
- U.S. entry into WWII
- Confirmed evidence smoking

Number of cigarettes
The House of Koop-1986

Bill Lynn (OSH), Dave Burns (Senior Editor), and Don Shopland (OSH)—Part of the 1986 SG Report team— in front of Dr. Koop’s house on the NIH campus.

Source: Jon Samet’s personal collection
Adult per-capita cigarette consumption and major smoking and health events, US, 1900-2012

1988

The Health Consequences Of Smoking
NICOTINE ADDICTION
a report of the Surgeon General
1988

U.S. entry into WWI
Great Depression begins
U.S. entry into WWII
Confluence evidence links smoking and health
1964 Surgeon General’s report on smoking and health
1986 Surgeon General’s report on secondhand smoke
1988 Surgeon General’s report on secondhand smoke
Broadcast ad ban
Nonsmokers’ rights movement begins
Synar Amendment enacted
Nicotine medications available over-the-counter
Master Settlement Agreement
Family Smoking Prevention and Tobacco Control Act
Cigarette price drop
FDA proposed rule
2006 Surgeon General’s report on secondhand smoke (an update)
Federal $1.01 tax increase
Adult per-capita cigarette consumption and major smoking and health events, US, 1900-2012
Adult per-capita cigarette consumption and major smoking and health events, US, 1900-2012
The 2004 SGR: It Takes a Village...
Adult per-capita cigarette consumption and major smoking and health events, US, 1900-2012

- U.S. entry into WWI
- Great Depression begins
- U.S. entry into WWII
- Confluence of evidence linking smoking and cancer
- Reassurance campaign begins
- Broadcast ad ban
- 1964 Surgeon General’s report on smoking and health
- Nonsmokers’ rights movement begins
- Cigarette drop
- Synar Amendment enacted
- Nicotine medications available over-the-counter
- Master Settlement Agreement
- Family Smoking Prevention and Tobacco Control Act
- FDA proposed rule
- Surgeon General’s report on secondhand smoke (an update)
- Federal $1.01 tax increase
- The Health Consequences of Involuntary Exposure to Tobacco Smoke
  A Report of the Surgeon General

Department of Health and Human Services
The 2006 SGR: The Release, June 27, 2006
4. The scientific evidence indicates that there is no risk-free level of exposure to secondhand smoke.

5. Many millions of Americans, both children and adults, are still exposed to secondhand smoke in their homes and workplaces, despite substantial progress in tobacco control.

6. Eliminating smoking in indoor spaces fully protects nonsmokers from exposure to secondhand smoke (separating smokers from nonsmokers, cleaning the air, and ventilating buildings cannot eliminate exposure of nonsmokers to secondhand smoke).
Adult per-capita cigarette consumption and major smoking and health events, US, 1900-2012
SGR 2010: Major conclusions

The scientific evidence supports the following major conclusions:

1. The evidence on the mechanisms by which smoking causes disease indicates that there is no risk-free level of exposure to tobacco smoke.

2. Inhaling the complex chemical mixture of combustion compounds in tobacco smoke causes adverse health outcomes, particularly cancer and cardiovascular and pulmonary diseases, through mechanisms that include DNA damage, inflammation, and oxidative stress.

3. Through multiple defined mechanisms, the risk and severity of many adverse health outcomes caused by smoking are directly related to the duration and level of exposure to tobacco smoke.

4. Sustained use and long-term exposures to tobacco smoke are due to the powerfully addicting effects of tobacco products, which are mediated by diverse actions of nicotine and perhaps other compounds, at multiple types of nicotinic receptors in the brain.

5. Low levels of exposure, including exposures to secondhand tobacco smoke, lead to a rapid and sharp increase in endothelial dysfunction and inflammation, which are implicated in acute cardiovascular events and thrombosis.

6. There is insufficient evidence that product modification strategies to lower emissions of specific toxicants in tobacco smoke reduce risk for the major adverse health outcomes.

USDHHS 2010
Adult per-capita cigarette consumption and major smoking and health events, US, 1900-2012
2014
Adult per-capita cigarette consumption and major smoking and health events, US, 1900-2012

- U.S. entry into WWI
- Great Depression begins
- U.S. entry into WWII
- Confluence of evidence linking smoking and cancer
- 1964 Surgeon General’s report on smoking and health
- Reassurance campaign begins
- Broadcast ad ban
- Fairness Doctrine messages on broadcast media
- Nonsmokers’ rights movement begins
- Federal cigarette tax doubles
- 1986 Surgeon General’s report on secondhand smoke
- Cigarette price drop
- FDA proposed rule
- 2006 Surgeon General’s report on secondhand smoke (an update)
- Federal $1.01 tax increase
- 2014
The Health Consequences of Smoking — 50 Years
ENOUGH IS ENOUGH!!!
Conclusion #1: The century-long epidemic of cigarette smoking has caused an enormous avoidable public health tragedy. Since the first Surgeon General’s report in 1964 more than 20 million premature deaths can be attributed to cigarette smoking.
Conclusion #2: The tobacco epidemic was initiated and has been sustained by the aggressive strategies of the tobacco industry, which has deliberately misled the public on the risks of smoking cigarettes.
Conclusions #3-6:

Since the 1964 Surgeon General’s report, cigarette smoking has been causally linked to diseases of nearly all organs of the body, to diminished health status, and to harm to the fetus. Even 50 years after the first Surgeon General’s report, research continues to newly identify diseases caused by smoking, including such common diseases as diabetes mellitus, rheumatoid arthritis, and colorectal cancer.

Exposure secondhand tobacco smoke has been causally linked to cancer, respiratory, and cardiovascular diseases, and to adverse effects on the health of infants and children.

The disease risks from smoking by women have risen sharply over the last 50 years and are now equal to those for men for lung cancer, chronic obstructive pulmonary disease, and cardiovascular diseases.

In addition to causing multiple diseases, cigarette smoking has many other adverse effects on the body, such as causing inflammation and impairing immune function.
Active Smoking

**Cancers**
- Oropharynx
- Larynx
- Esophagus
- Trachea, bronchus, and lung
- Acute myeloid leukemia
- Stomach
- Liver
- Pancreas
- Kidney and ureter
- Cervix
- Bladder
- Colorectal

**Chronic Diseases**
- Stroke
- Blindness, cataracts, age-related macular degeneration
- Congenital defects—maternal smoking: orofacial clefts
- Periodontitis
- Aortic aneurysm, early abdominal aortic aneurysm
- Atherosclerosis in young adults
- Coronary heart disease
- Pneumonia
- Atherosclerotic peripheral vascular disease
- Chronic obstructive pulmonary disease, tuberculosis, asthma, and other respiratory effects
- Diabetes
- Reproductive effects in women (including reduced fertility)
- Hip fractures
- Ectopic pregnancy
- Male sexual function—erectile dysfunction
- Rheumatoid arthritis
- Immune function
  - Overall diminished health

*Source: USDHHS 2014*
Passive Smoking

**Children**
- Middle ear disease
- Respiratory symptoms, impaired lung function
- Lower respiratory illness
- Sudden infant death syndrome

**Adults**
- Stroke
- Nasal irritation
- Lung cancer
- Coronary heart disease
- Reproductive effects in women: low birth weight

Source: USDHHS 2014
Conclusions #7-9: Although cigarette smoking has declined significantly since 1964, very large disparities in tobacco use remain across groups defined by race, ethnicity, educational level, and socioeconomic status and across regions of the country.

Since the 1964 Surgeon General’s report, comprehensive tobacco control programs and policies have been proven effective for controlling tobacco use. Further gains can be made with the full, forceful, and sustained use of these measures.

The burden of death and disease from tobacco use in the United States is overwhelmingly caused by cigarettes and other combusted tobacco products; rapid elimination of their use will dramatically reduce this burden.
Chapter Conclusions:

1. Together, experience since 1964 and results from models exploring future scenarios of tobacco control indicate that the decline in tobacco use over coming decades will not be sufficiently rapid to meet targets. The goal of ending the tragic burden of avoidable disease and premature death will not be met quickly enough without additional action.

2. Evidence-based tobacco control interventions that are effective continue to be underutilized and implemented at far below funding levels recommended by the Centers for Disease Control and Prevention. Implementing tobacco control policies and programs as recommended by Ending the Tobacco Epidemic: A Tobacco Control Strategic Plan by the U.S. Department of Health and Human Services and the Ending the Tobacco Problem: A Blueprint for the Nation by the Institute of Medicine on a sustained basis at high intensity would accelerate the decline of tobacco use in youth and adults, and also accelerate progress toward the goal of ending the tobacco epidemic.

3. New “end game” strategies have been proposed with the goal of eliminating tobacco smoking. Some of these strategies may prove useful for the United States, particularly reduction of the nicotine content of tobacco products and greater restrictions on sales (including bans on entire categories of tobacco products).
Key policy messages:

- Counteracting industry marketing by sustaining high impact national media campaigns like the CDC’s Tips from Former Smokers campaign and FDA’s youth prevention campaigns at a high frequency level and exposure for 12 months a year for a decade or more;
- Raising the average excise cigarette taxes to prevent youth from starting smoking and encouraging smokers to quit;
- Fulfilling the opportunity of the Affordable Care Act to provide access to barrier-free proven tobacco use cessation treatment including counseling and medication to all smokers, especially those with significant mental and physical comorbidities;
- Expanding smoking cessation for all smokers in primary and specialty care settings by having health care providers and systems examine how they can establish a strong standard of care for these effective treatments;
- Effective implementation of FDA’s authority for tobacco product regulation in order to reduce tobacco product addictiveness and harmfulness;
- Expanding tobacco control and prevention research efforts to increase understanding of the ever changing tobacco control landscape;
- Fully funding comprehensive statewide tobacco control programs at CDC recommended levels; and
- Extending comprehensive smokefree indoor protections to 100% of the U.S. population.
Looking Ahead: Chapter 16

• Rapid reduction of combustible products
• Reduction of nicotine content in cigarettes
• Role of non-combustible products
  – Under Tobacco Control Act
  – Individual harm reduction vs. Population risk
• Using all strategies better and in concert
LET'S MAKE THE NEXT GENERATION
TOBACCO-FREE

Your Guide to the 50th Anniversary Surgeon General's Report on Smoking and Health

U.S. Department of Health and Human Services
Looking Ahead: Now

• Are we at a “tipping point”?
  – FDA regulatory and public health activities.
  – E-cigarettes and other potential harm reduction products.
  – Some of the “epidemics” are ending, but others are not.
Promise and Peril of e-Cigarettes
Can Disruptive Technology Make Cigarettes Obsolete?

Despite extraordinary success, progress has stalled in reducing premature deaths from tobacco (primarily caused by cigarettes or other combusting tobacco products and not by nicotine per se). The dominance of cigarettes over the past 100 years (the cigarette century) threatens to persist for another century.

Two philosophies have dominated tobacco control: abstinence and harm reduction. Abstinence implies avoiding all tobacco use behavior because there is no safe tobacco or nicotine level. If avoidance is not practical or realistic, harm reduction sets a goal that minimizes the harm caused by the behavior. Tension between reduction and abstinence advocates can be divisive. The rapid rise in the use and popularity of e-cigarettes has substantially increased this tension because of their potential for harm reduction. Although still variable in quality, appeal, and efficient nicotine delivery in products that deliver cleaner nicotine in a safe, appealing mode. Whether this can be translated into a sustained disruptive technology depends on factors including innovation of better products, enhanced labeling and marketing, and appropriate regulation and policy implementation.

US Food and Drug Administration Regulation
Product regulation is essential to minimize unintended consequences and to appropriately reassure consumers. However, regulations should not be so burdensome as to stifle innovation and independent manufacturers. A comprehensive nicotine regulatory policy is needed from the US Food and Drug Administration (FDA). Embracing harm reduction, the director of the FDA's Center for Tobacco Products (CTP) proposed a continuum of risk, with combustible products (eg, cigarettes, cigars, and hoo-
The Emergence of Tobacco Regulatory Science

• “…research that is needed to ensure that U.S. tobacco regulatory actions and activities are based on sound and relevant scientific evidence.” (TCORS¹)

• Research with a purpose and directed at FDA priorities

• Mechanisms include the TCORS and grants and FDA research

Pushing for the “End Game”

• What is the “End Game”?  
  – The end of use of combustible products?  
  – The end of nicotine addiction?

• How will we get there?  
  – “Smokefree generations”  
  – “Sinking lid”  
  – “Smoking licenses”
Endgame proposals

- Minimising the harm from nicotine use: finding the right regulatory framework
  Ron Borland
  *Tob Control* 2013;22:i6-i9 doi:10.1136/tobaccocontrol-2012-050843
  [Abstract] [Full text] [PDF] [Request permissions] OPEN ACCESS

- Supply-side options for an endgame for the tobacco industry
  Cynthia D Callard, Neil E Collishaw
  *Tob Control* 2013;22:i10-i13 doi:10.1136/tobaccocontrol-2012-050863
  [Abstract] [Full text] [PDF] [Request permissions] OPEN ACCESS

- Reducing the nicotine content to make cigarettes less addictive
  Neal L Benowitz, Jack E Henningfield
  *Tob Control* 2013;22:i14-i17 doi:10.1136/tobaccocontrol-2012-050860
  [Abstract] [Full text] [PDF] [Request permissions] OPEN ACCESS

- Potential advantages and disadvantages of an endgame strategy: a ‘sinking lid’ on tobacco supply
  Nick Wilson, George W Thomson, Richard Edwards, Tony Blakely
  *Tob Control* 2013;22:i18-i21 doi:10.1136/tobaccocontrol-2012-050791
  [Abstract] [Full text] [PDF] [Request permissions] OPEN ACCESS

- The tobacco-free generation proposal
  A J Berrick
  *Tob Control* 2013;22:i22-i26 doi:10.1136/tobaccocontrol-2012-050865
  [Abstract] [Full text] [PDF] [Request permissions] OPEN ACCESS
Conference Declaration
Towards a tobacco-free world

We, the participants of this conference:

R.ecognize the enormous adverse impact of the tobacco epidemic, globally and particularly in low-and middle income countries and the need to hasten tobacco control efforts across the world.

O bserv e that despite effective, evidence-based tobacco control policies, reduction in smoking prevalence in developed countries has started to slow down and use of smoked and smokeless tobacco continues to increase in many low-and middle income countries.

I dentify the tobacco epidemic as a global threat to equitable social and economic development and recognize the need to integrate tobacco control into the global discourse on the post-2015 sustainable development goals.

E mphasize that multi-sectoral integration, inter-agency coordination and wide ranging partnerships remain central to fighting the tobacco epidemic and countering the tobacco industry interference.

E xpress concern about the debilitating nature of tobacco farming, production and manufacturing, associated human rights violations and call for policies to support transition from tobacco to other livelihoods.

Our Vision: To make the 21st Century the last period in history where any harm is caused to humans by tobacco.

Our view of The 'Endgame' A composite of strategies to reduce or contain the prevalence of tobacco use to less than 5%, which is a tipping point of de-normalisation, at which countries are enabled to further completely eliminate all forms of tobacco consumption.

Source: http://www.endgameconference2013.in
Hierarchies for Tobacco Control Research

Global-level (Globalization of tobacco industry/FCTC)

Macro-level (Regulation of tobacco industry)

Mezzo-level (Smoke-free work & leisure environments)

Micro-level (Smoking habits of friends, family)

Genomic substrate – $\alpha_1$ AT deficiency, susceptibility to addiction

Sub-cellular/molecular level – Metabolic activity

Cellular level – Status of nicotine receptors

Multi-organ system level – Nicotine addiction

Expression

Embodiment

Opportunities

Constraints

TIME AXIS

Upstream
Conception/early-life

Down-hill/Above water

Underwater

Macro-level (Regulation of tobacco industry)

Mezzo-level (Smoke-free work & leisure environments)

Micro-level (Smoking habits of friends, family)

Genomic substrate – $\alpha_1$ AT deficiency, susceptibility to addiction

Sub-cellular/molecular level – Metabolic activity

Cellular level – Status of nicotine receptors

Multi-organ system level – Nicotine addiction

Expression

Embodiment

Opportunities

Constraints

TIME AXIS
Implications for Researchers

• Post the 50th Anniversary SG report what questions do we want to answer?
  – Related to disease causation?
  – Related to nicotine addiction?
  – Related to genetics?
  – Related to policy approaches?
Adult per-capita cigarette consumption and major smoking and health events, US, 1900-2064