Smoking Cessation Leadership Center

UCSF

University of California San Francisco

Reducing the Nicotine Content of Cigarettes and the Tobacco Endgame

Neal L. Benowitz, MD, Emeritus Professor of Medicine and Bioengineering & Therapeutic Sciences, University of California, San Francisco

February 16, 2023

Moderator

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Smoking Cessation Leadership Center
University of California, San Francisco

A National Center of Excellence for Tobacco-Free Recovery

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- For technical assistance please contact (877) 509-3786 or Jessica.Safier@ucsf.edu.
- Visit CABHWI.ucsf.edu for more information

Today's Presenter

Neal L. Benowitz, MD

Emeritus Professor of Medicine and
Bioengineering & Therapeutic Sciences

University of California, San Francisco

Reducing the Nicotine Content of Cigarettes and the Tobacco Endgame

Neal L Benowitz MD
Professor of Medicine
University of California
San Francisco

SCLC Webinar
Feb 16, 2023

UCSF Center for Tobacco Control Research and Education

Conflict of Interest Statement

- I am a consultant to Pfizer and Achieve Life Sciences, companies that market or are developing smoking cessation medications.
- I serve as an expert witness in litigation against tobacco companies

THE WALL STREET JOURNAL.

WSJ NEWS EXCLUSIVE | HEALTH POLICY

Biden Administration Considering Rule to Cut Nicotine in Cigarettes

Policy could be paired with proposal to ban menthols; FDA must decide whether to pursue menthol ban by April 29

The nicotine-reduction proposal under discussion would aim to push millions of U.S. smokers to quit or switch to less harmful alternatives.

PHOTO: BOBBY CALVAN/ASSOCIATED PRESS

By Jennifer Maloney

Updated April 19, 2021 6:21 pm ET

WSJ, April 19, 2021

The Combustible Tobacco Endgame

Strategy to eradicate or reduce to minimal levels the use of (and disease caused by) combustible tobacco products.

Outline

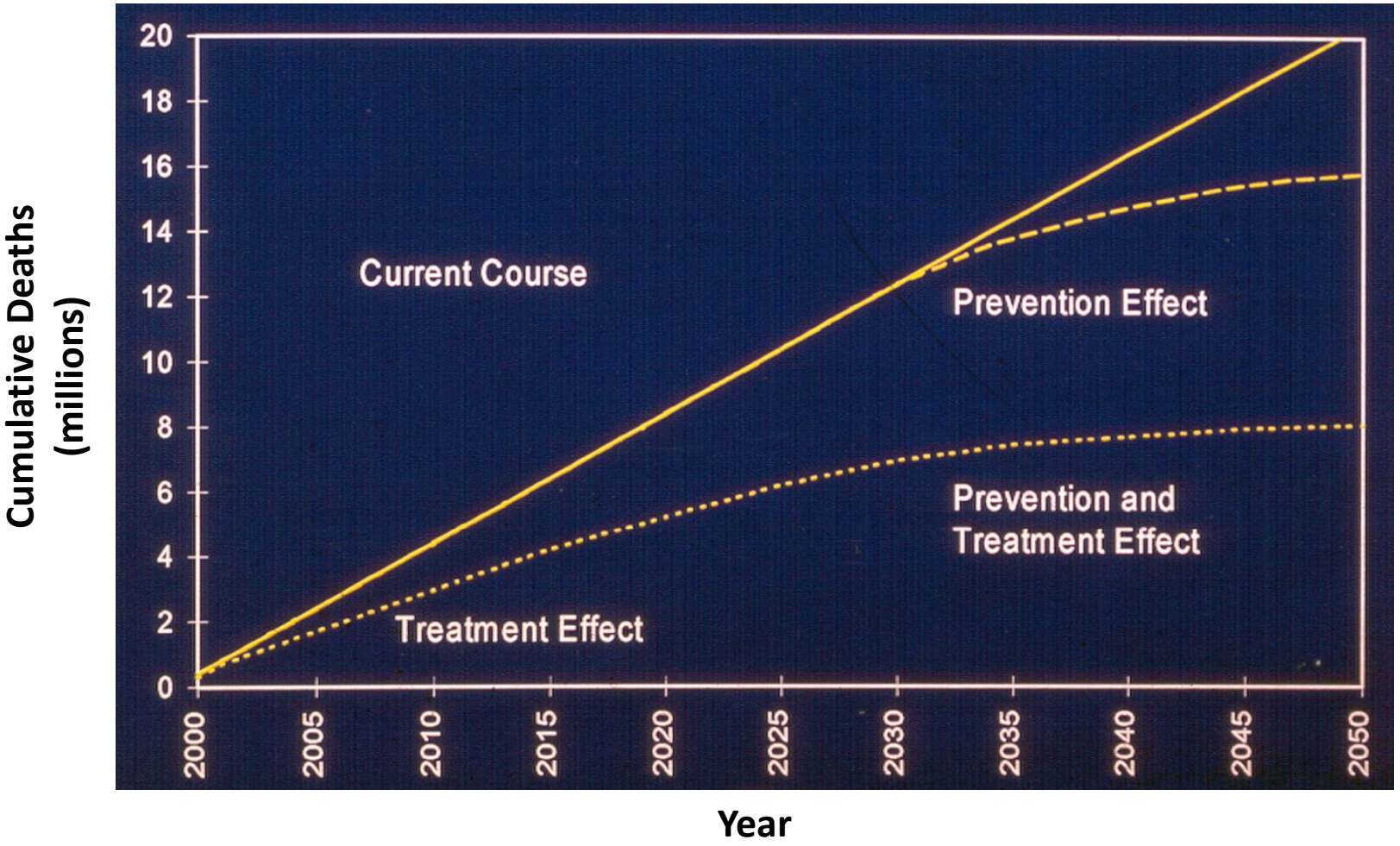
- Enhancing smoking cessation
- Nicotine pharmacology and public policy
- History of the nicotine reduction intervention
- Nicotine reduction research findings
- Implementing a nicotine reduction intervention

Major causes of death in U.S. 2016
All are smoking-related

1. Ischemic heart disease
2. Lung cancer
3. Chronic obst lung disease
4. Alzheimer /dementias
5. Colo-rectal cancer
6. Motor vehicle injuries
7. Lower respir tract infections
8. Diabetes
9. Intracerebral hemorrhage
10. Ischemic stroke

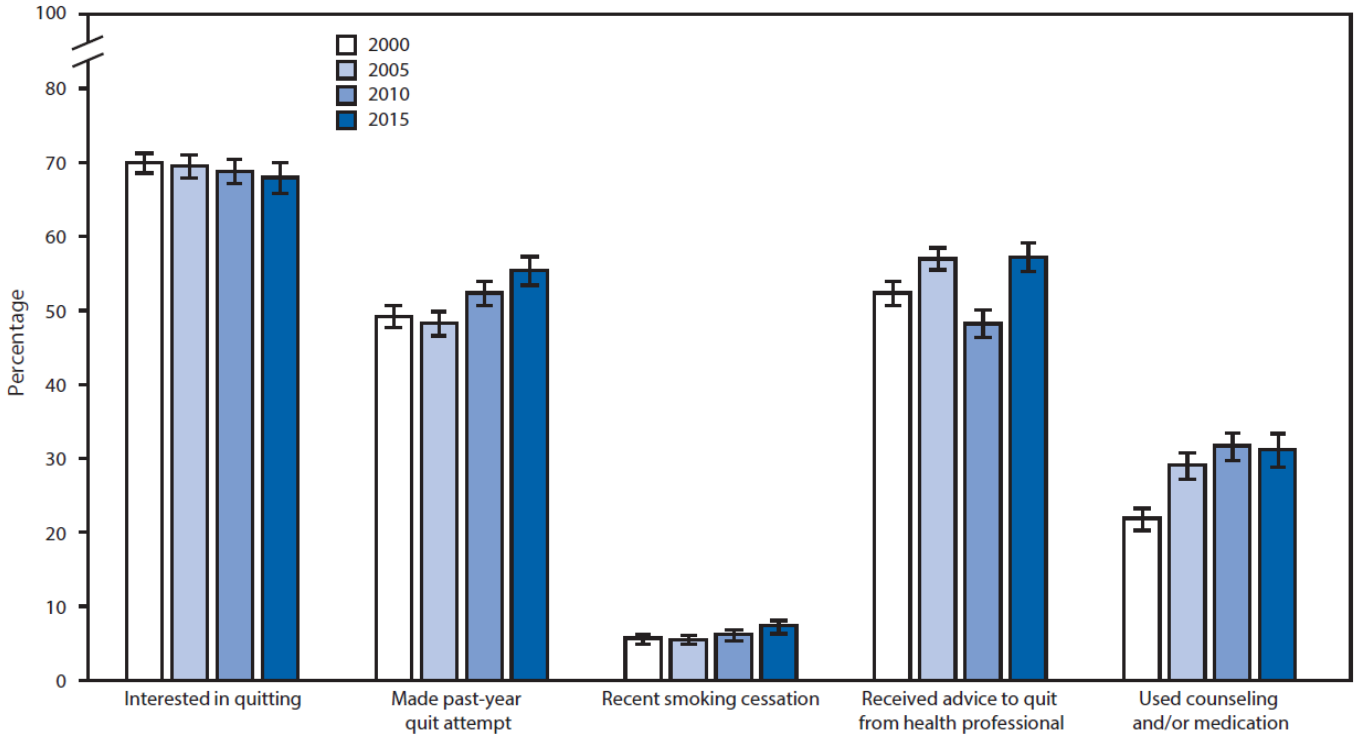
Getting smokers to quit as soon as possible is essential for public health

Projected Global Mortality from Smoking 2000-2050



Henningfield and Slade, FDLI, 1998

Despite interest in quitting, smoking cessation rates have remained low for > 15 years



Babb et al. MMWR 2017

Enhancing Quitting

- **Denormalization of smoking** (constriction of social networks)
- **Traditional smoking cessation interventions** (counseling, pharmacotherapy, quit lines, media interventions)
- **Tobacco harm reduction** (electronic nicotine delivery devices; other non-combusted nicotine products)
- **Tobacco product regulation** (nicotine-focused)

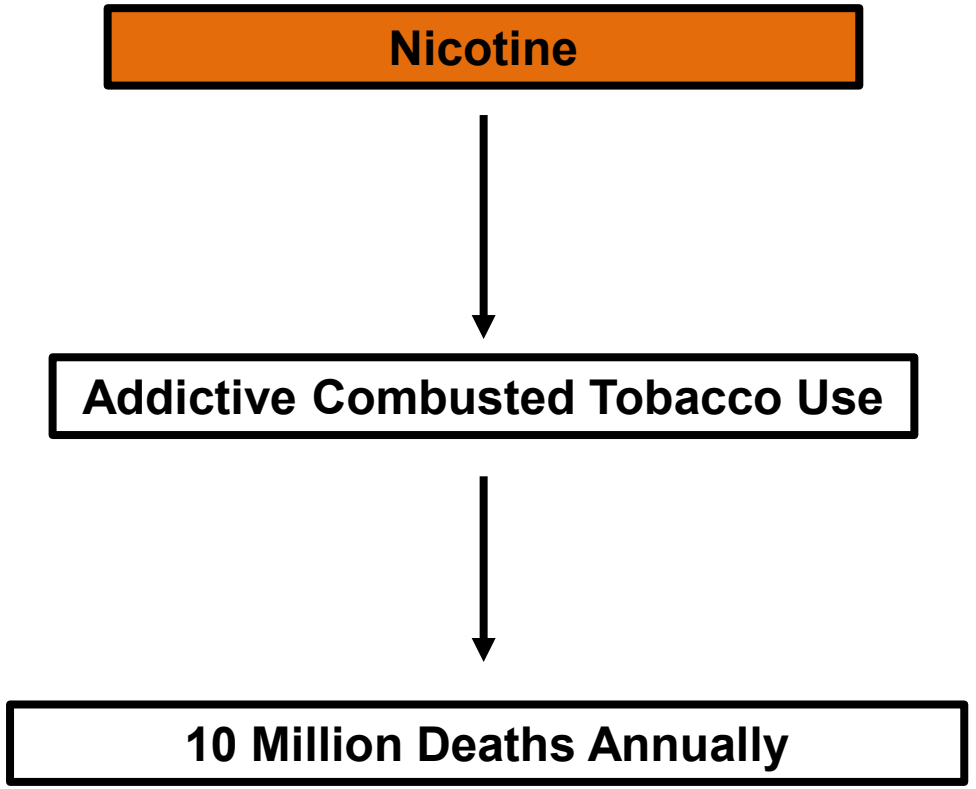
Beliefs Underlying Endgame Strategies

- **The status quo is unacceptable**
- **Reducing smoking substantially will require something new, bold and fundamentally different**

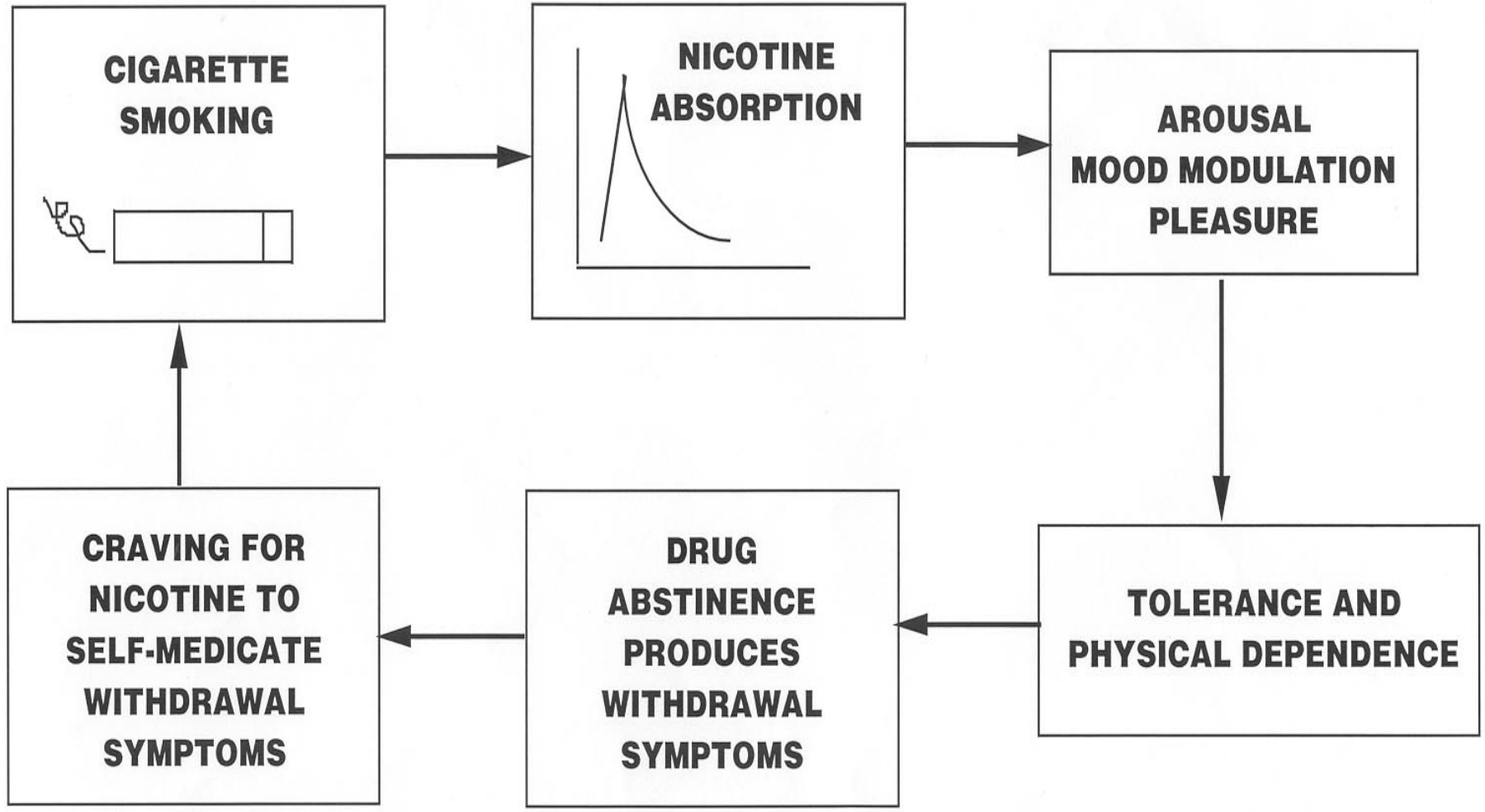
Warner Tob Control 2013

Nicotine Pharmacology and Public Policy

Tobacco Combustion Products Responsible for Most Tobacco-related Disease, but People Smoke for Nicotine



NICOTINE ADDICTION CYCLE



Major Safety Concerns for Nicotine

• Addiction	• Definite
• Cardiovascular disease	• Probable
• Reproductive Toxicity	• Probable
• Impaired Adolescent Brain development	• Possible
• Infectious Disease Risk	• Possible
• Cancer	• Possible
• COPD	• Unlikely

UCSF Center for Tobacco Control Research and Education

Why cigarettes are so harmful

Cigarettes (and other combusted tobacco products) are particularly harmful because they are highly addictive. Addiction means loss of control of drug use. 70% of cigarette smokers are daily smokers and rarely go through a day with smoking

The harms of nicotine

Nicotine per se is not harmless, but is much less harmful that inhaling smoke containing combustion toxins. The primary harm of nicotine is the addiction that sustains combusted tobacco use.

The History of the Nicotine Reduction Intervention

A Workplace Smoking Ban Is Proposed

Continued From Page 1

Commissioner of Food and Drugs, testified that one tobacco company, which he would not identify, had suppressed its own research that indicated that nicotine was addictive in animal studies.

Banning nicotine, Mr. Waxman said, is "starting to look like it might well be a reasonable way to deal with this problem."

Eliminating nicotine and thereby removing the addictive property, he added, would allow those who wanted to quit to do so and would provide more of a choice to those who wanted to continue to smoke, rather than forcing them to continue by virtue of their addiction.

However, removing nicotine would not necessarily reduce the health risks associated with smoking.

Another Era of Prohibition?

The tobacco industry strenuously objected to today's anti-smoking pronouncements, the latest in a persistent

Nicotine in cigarettes and smokeless tobacco is a drug and these products are nicotine delivery devices under the Federal Food, Drug, and Cosmetic Act.

U.S. Food and Drug Administration
Fed. Reg. Vol. 60, No. 155
Aug. 11, 1995

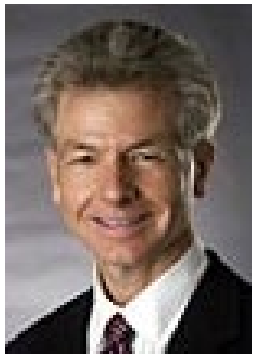
Establishing a Nicotine Threshold for Addiction

- **Goal:**
  - To prevent nicotine addiction in youth.
- **Threshold for Addiction:**
  - Dose to establish and maintain addiction

    ~ 5 mg/day.
- **Proposal:**
  - A gradual reduction of nicotine content of cigarettes over 10-15 years.

The NEW ENGLAND JOURNAL of MEDICINE

Benowitz NL, Henningfield JE. Establishing a nicotine threshold for addiction. The implications for tobacco regulation. (1994) *N Engl J Med, 331*(2), 123-125.



Family Smoking Prevention and Tobacco Control Act (P.L.111-31) 2009

FDA Regulation of Tobacco Product Characteristics

- **Authority to promulgate tobacco product standards as appropriate to protection of public health.**

- **Authority to reduce nicotine yields of the product as long as it does not require total nicotine to be reduced to “zero.”**

The NEW ENGLAND JOURNAL of MEDICINE

PERSPECTIVE

A Nicotine-Focused Framework for Public Health

Scott Gottlieb, M.D., and Mitchell Zeller, J.D.

Despite extraordinary progress in tobacco control and prevention, tobacco use remains the leading cause of preventable disease and death in the United States. Combustible cigarettes cause the overwhelming majority of tobacco-related disease and are responsible for more than 480,000 U.S. deaths each year. Indeed, when used as intended, combustible cigarettes kill half of all long-term users.[1] With the tools provided to the Food and Drug Administration (FDA) under the Family Smoking Prevention and Tobacco Control Act of 2009, the agency has taken consequential steps to prevent sales of tobacco products to children, expand the science base for understanding traditional and newer tobacco products, and conduct public education campaigns. But the agency needs to do more to protect Americans;

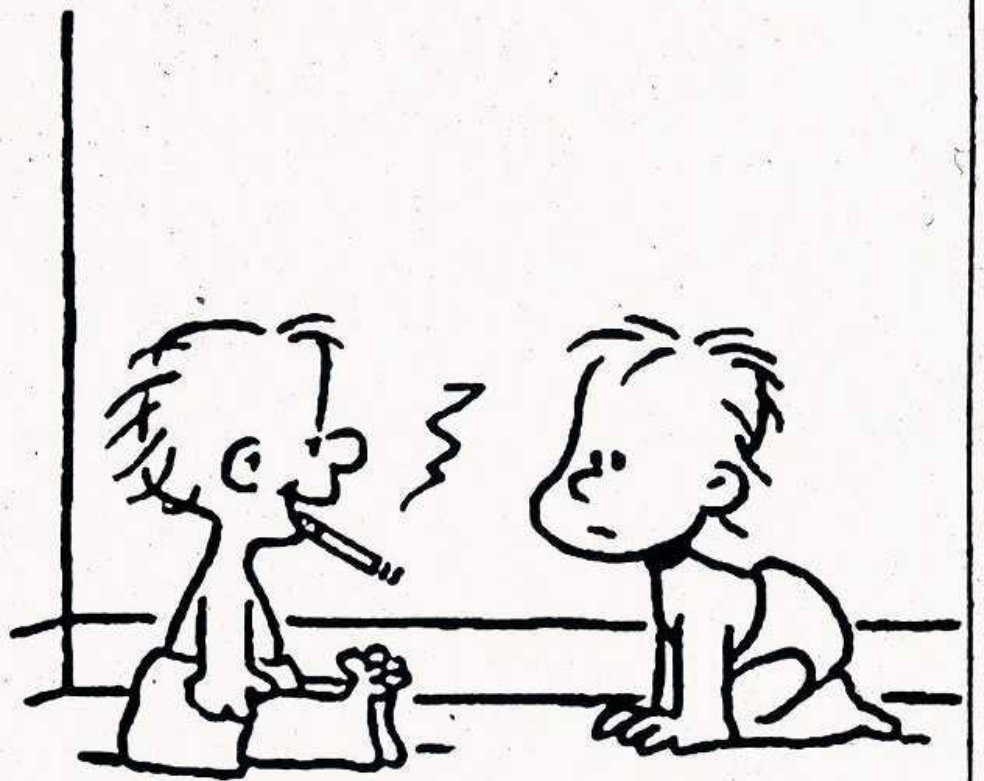
Gottlieb and Zeller, NEJM, 2016

FDA Regulatory Framework with a Focus on Nicotine

- Smoking causes 480,000 deaths per year
- The core problem is not nicotine itself, but the delivery mechanism (combustible tobacco)
- Goal to reduce the addictiveness of cigarettes
- Focus on nicotine and support innovation to promote harm reduction
- Consider the continuum of risk of nicotine-containing products

Reducing the Nicotine Content to Make Cigarettes Less Addictive

Berry's World



"Don't worry! I can quit any time I want."

Rationale for reducing nicotine in cigarette tobacco

The initial rationale was to prevent children who experiment with smoking from becoming addicted later in life. To provide freedom of choice.

Another benefit would be that addicted smokers, most of whom would like to quit, will move toward cessation.

Tobacco Control 1998;7:281–293

FROM THE AMERICAN MEDICAL ASSOCIATION

Reducing the addictiveness of cigarettes

Jack E Henningfield, Neal L Benowitz, John Slade, Thomas P Houston, Ronald M Davis, and Scott D Deitchman, for the Council on Scientific Affairs, American Medical Association

AMA recommends

FDA authority over tobacco products

Product modifications to make cigarettes less addictive

FDA requires reduced addictiveness within 5-10 yrs

Support expanded access to smoking cessation treatment and strengthening of the treatment infrastructure

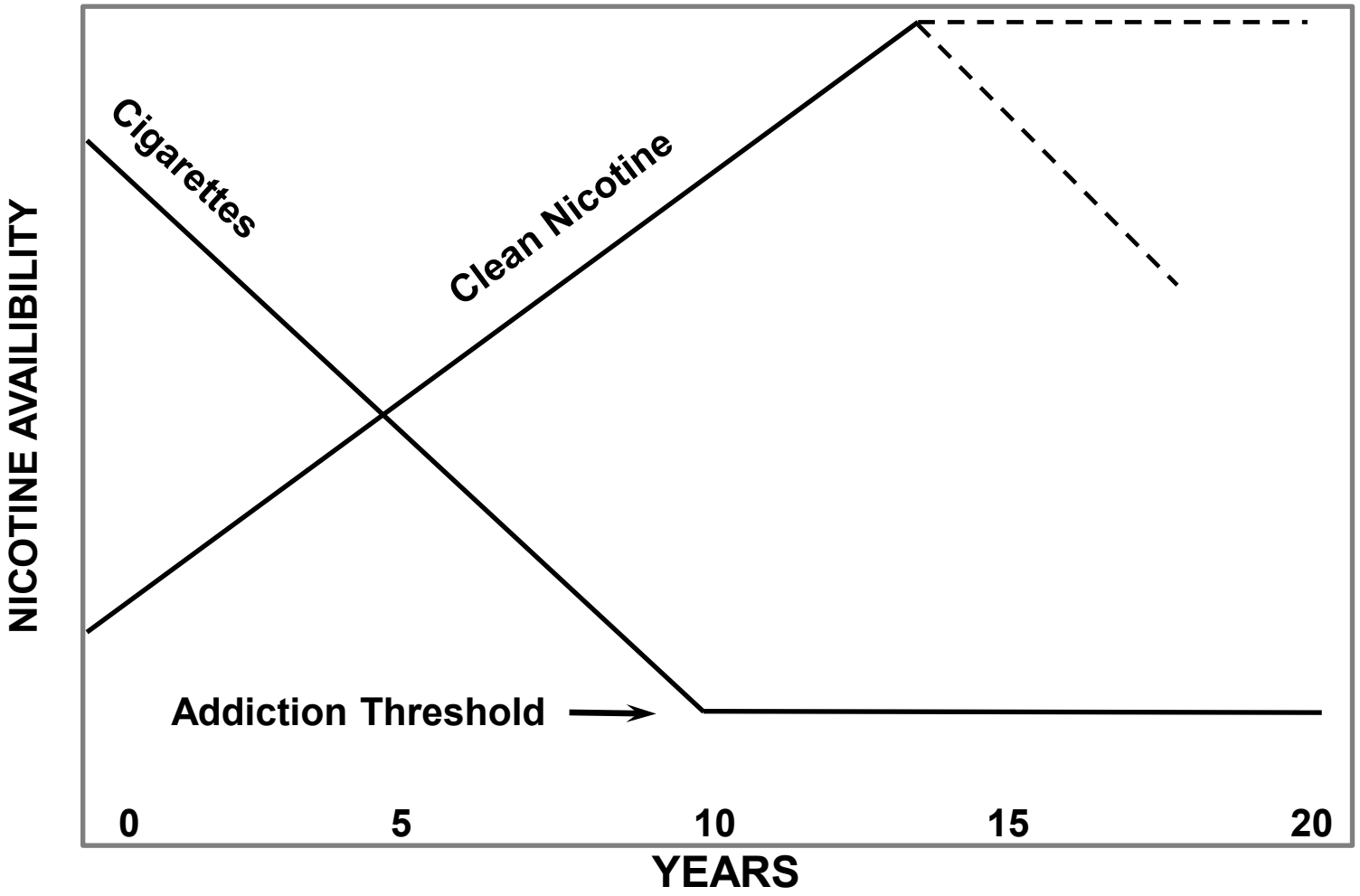
These are not reduced nicotine content cigarettes

FTC Machine Test Method

“Light commercial brand cigarettes are not reduced nicotine cigarettes”

Reduced nicotine yield by machine testing is related to faster burning and greater ventilation. The nicotine content of cigarette filler is the same. Smokers can easily compensate by taking more frequent puffs and blocking ventilation holes.

Reducing Addictiveness of Cigarettes: A Nicotine Reduction Strategy



The extent of nicotine reduction across cigarette brands and other forms of combustible tobacco (roll your own, little cigars, pipe tobacco) must be uniform.

Nicotine Yield Reduction Studies

Cancer Epidemiology, Biomarkers & Prevention

Global Perspectives

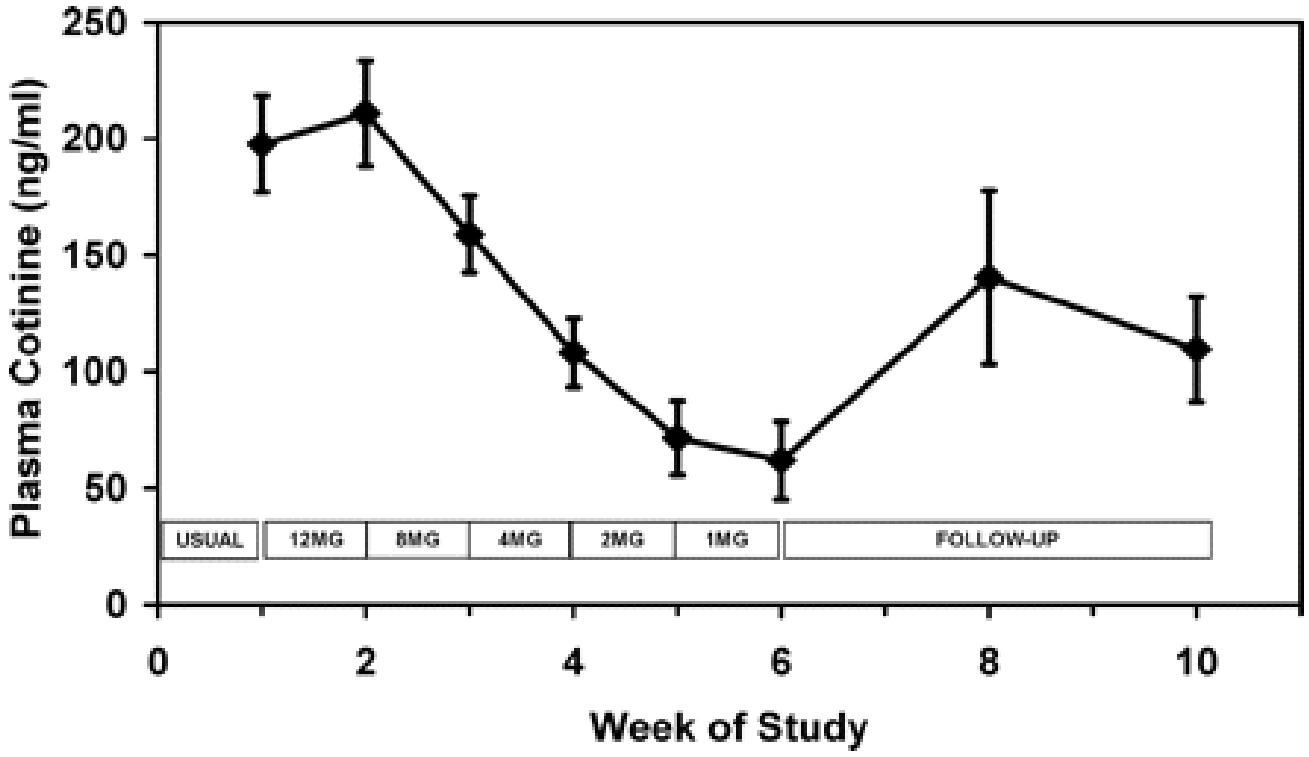
Nicotine and Carcinogen Exposure with Smoking of Progressively Reduced Nicotine Content Cigarette

Neal L. Benowitz, Sharon M. Hall, Susan Stewart, Margaret Wilson, Delia Dempsey, and Peyton Jacob III

Division of Clinical Pharmacology and Experimental Therapeutics, Medical Service, San Francisco General Hospital Medical Center, Departments of Medicine, Psychiatry, and Biopharmaceutical Sciences, University of California, San Francisco, California

Benowitz et al., CEBP, 2007

6-week Nicotine Content Taper: 75% reduction in nicotine intake

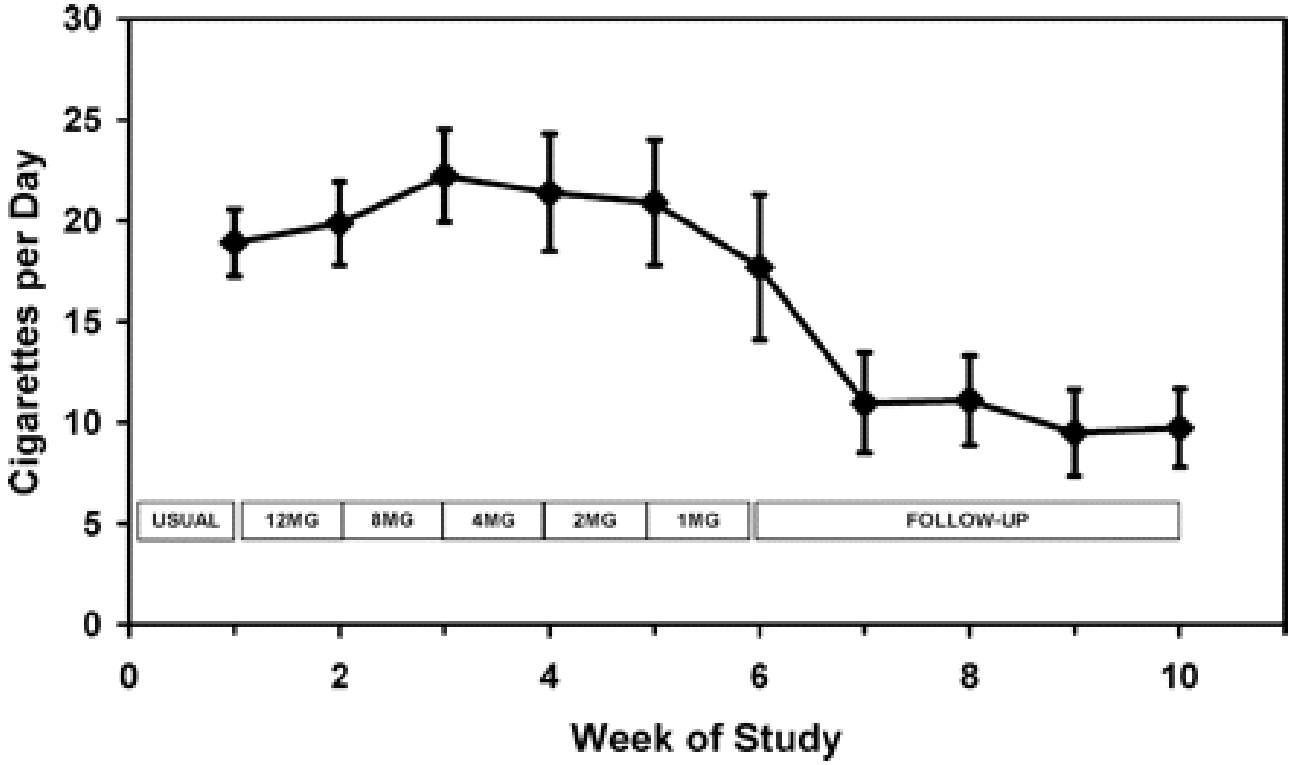


Benowitz et al, CEBP 2007; 16:2479

Quotes from Reduced Nicotine Content Cigarette Smokers

- **“I no longer feel the need to have coffee and cigarettes first thing in the morning.”**
- **“experiencing less craving”**
- **“smoking these cigarettes are like quitting and therefore, might as well quit.”**
- **“smoking is losing its pleasure”.**

Evidence of reduced nicotine dependence



Benowitz et al, CEBP 2007; 16:2479

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SPECIAL ARTICLE

Randomized Trial of Reduced-Nicotine Standards for Cigarettes

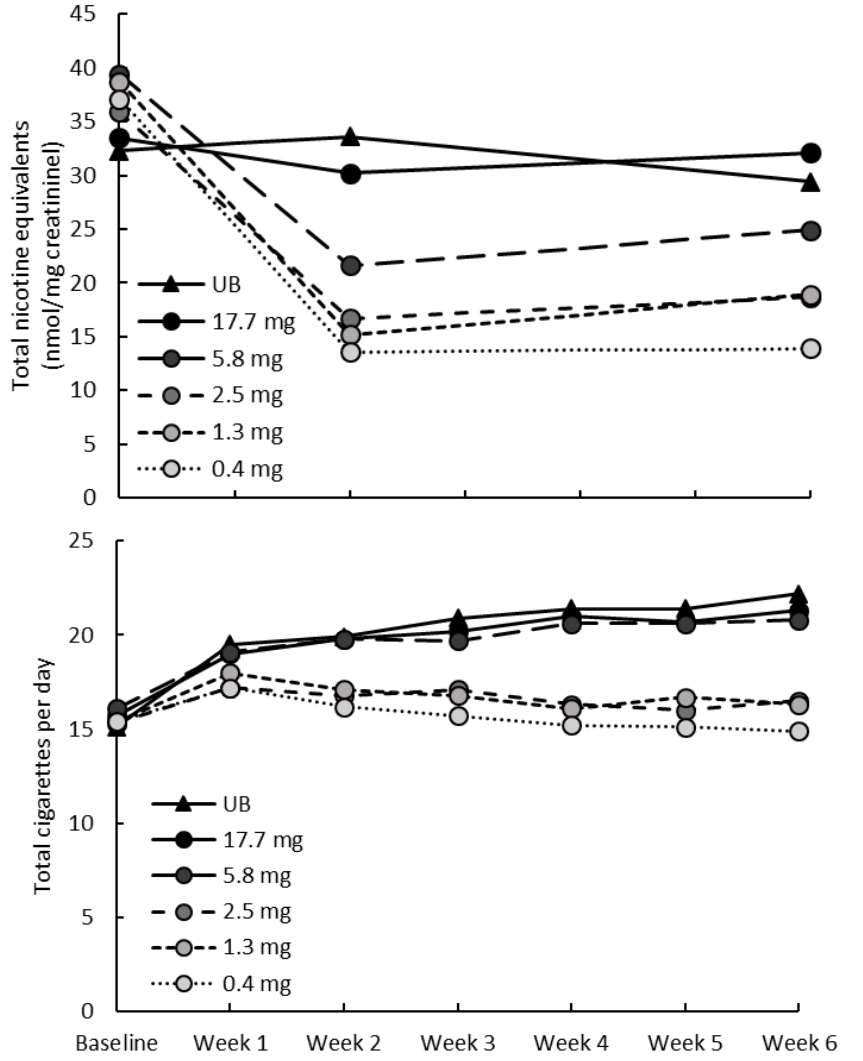
Eric C. Donny, Ph.D., Rachel L. Denlinger, B.S., Jennifer W. Tidey, Ph.D., Joseph S. Koopmeiners, Ph.D., Neal L. Benowitz, M.D., Ryan G. Vandrey, Ph.D., Mustafa al'Absi, Ph.D., Steven G. Carmella, B.A., Paul M. Cinciripini, Ph.D., Sarah S. Dermody, M.S., David J. Drobes, Ph.D., Stephen S. Hecht, Ph.D., Joni Jensen, M.P.H., Tonya Lane, M.Ed., Chap T. Le, Ph.D., F. Joseph McClernon, Ph.D., Ivan D. Montoya, M.D., M.P.H., Sharon E. Murphy, Ph.D., Jason D. Robinson, Ph.D., Maxine L. Stitzer, Ph.D., Andrew A. Strasser, Ph.D., Hilary Tindle, M.D., M.P.H., and Dorothy K. Hatsukami, Ph.D.

Donny et al., NEJM, 2015

Sudden Nicotine Content Reduction Comparing Cigarettes with Different Nicotine Content

Threshold dose to reduce addictiveness is ≤ 0.4 mg/g tobacco

- **70% reduced nicotine intake**
- **Reduced cigarettes smoked**
- **Reduced dependence and urges**
- **Increased quit attempts**
- **No compensatory smoking**
- **Did not lead to greater use of substances of abuse or increase in depressed mood.**



Donny et al., NEJM, 2015

Research

JAMA | Original Investigation

Effect of Immediate vs Gradual Reduction in Nicotine Content of Cigarettes on Biomarkers of Smoke Exposure

A Randomized Clinical Trial

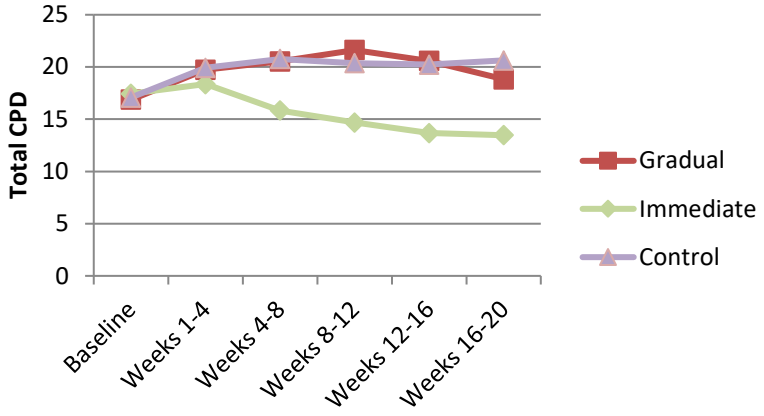
Dorothy K. Hatsukami, PhD; Xianghua Luo, PhD; Joni A. Jensen, MPH; Mustafa al'Absi, PhD; Sharon S. Allen, MD; Steven G. Carmella, BA; Menglan Chen, MS; Paul M. Cinciripini, PhD; Rachel Denlinger-Apte, MPH; David J. Drobes, PhD; Joseph S. Koopmeiners, PhD; Tonya Lane, MEd; Chap T. Le, PhD; Scott Leischow, PhD; Kai Luo, PhD; F. Joseph McClernon, PhD; Sharon E. Murphy, PhD; Viviana Paiano, MS; Jason D. Robinson, PhD; Herbert Severson, PhD; Christopher Sipe, MS; Andrew A. Strasser, PhD; Lori G. Strayer, MPH; Mei Kuen Tang, BS; Ryan Vandrey, PhD; Stephen S. Hecht, PhD; Neal L. Benowitz, MD; Eric C. Donny, PhD

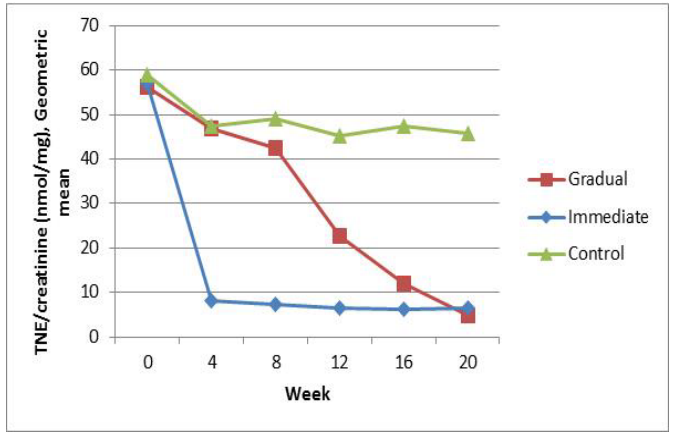
Hatsukami et al., JAMA, 2018

Benefits of Immediate vs Gradual Nicotine Reduction: Nicotine Intake and CPD

Immediate vs. gradual nicotine reduction and smoking normal nicotine content cigarettes resulted in:

- **Greater reductions in cigarettes per day (CPD)**
- **Greater reductions in nicotine exposure**



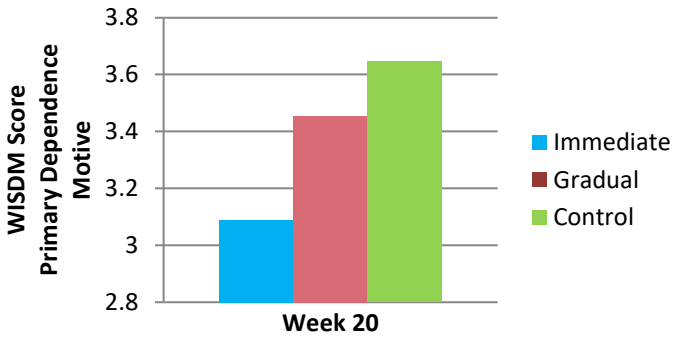


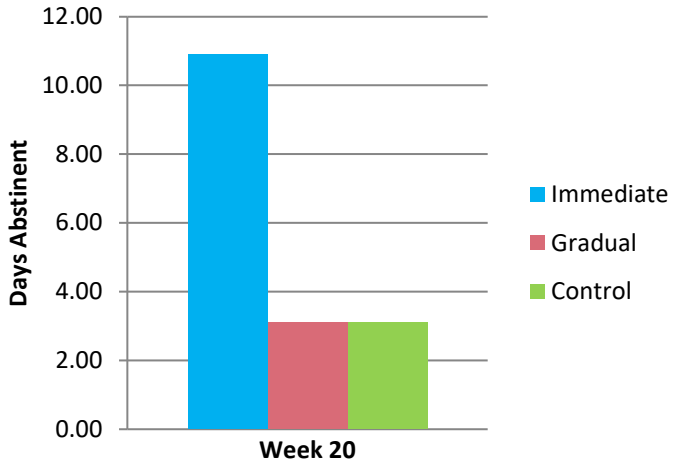
Benefits of immediate nicotine reduction: reduced level of dependence and more days of smoking abstinence

Immediate vs. gradual nicotine reduction and smoking normal nicotine content cigarettes resulted in:

- Greater decreases in dependence
- Higher rates and duration of abstinence

*WISDM: Wisconsin Inventory of Smoking Dependence Motives





What about compensation?

When smokers switch to commercial low yield cigarettes that compensate to maintain desired nicotine intake.

When smokers switch to very low nicotine cigarettes, compensation is impossible, and they reduce their daily intake of nicotine.

Several clinical trials document no increase in exposure to harmful combustion toxins when switching to very low nicotine cigarettes

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
21 CFR Part 1130
[Docket No. FDA–2017–N–6189]
RIN 0910–AH86

Tobacco Product Standard for Nicotine Level of Combusted Cigarettes

AGENCY: Food and Drug Administration, HHS.
ACTION: Advance notice of proposed rulemaking.

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WSJ NEWS EXCLUSIVE | HEALTH POLICY

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Policy could be paired with proposal to ban menthols; FDA must decide whether to pursue menthol ban by April 29

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PHOTO: BOBBY CALVAN/ASSOCIATED PRESS

By Jennifer Maloney

Updated April 19, 2021 6:21 pm ET

WSJ, April 19, 2021

New York Times
June 21, 2022

F.D.A. Aims to Cut Down on Smoking by Slashing Nicotine Levels in Cigarettes

The move would be an effort to further wean Americans from addictive tobacco products and reduce smoking-related illnesses.

Criticisms of mandated nicotine reduction

- RCTs do not represent real world smokers
- Prohibition – another “war on drugs”?
- Black market/undesirable workarounds
- Personal autonomy – should public health policy be coercive?
- Harmful to people with mental illness – such as ADHD?

Is nicotine reduction nicotine prohibition?

Prohibition has not worked for other drugs such as alcohol and cannabis.

Smokers need to be educated that nicotine is not being prohibited, but rather the harmful delivery system for nicotine is prohibited.

Other less harmful forms of nicotine will still be available for those who need nicotine.

Implementing a Nicotine Reduction Intervention

Components of a Cigarette Nicotine Reduction Strategy: Impact on Smoking Cessation Infrastructure

- **Education: Public and Medical**
- **Access to tobacco dependence treatment/treatment infrastructure: millions of smokers needing assistance in a short period of time**
- **Surveillance: changes in cigarette consumption, rates of tobacco use initiation among youth, unexpected consequences**
- **Ready availability of alternative non-combusted nicotine products**

Possible adjuncts to Nicotine Reduction in Cigarettes

- Nicotine replacement medications
- Non-combustible tobacco products
- Electronic nicotine delivery devices
- Differential Taxation

ADDICTION

SSA SOCIETY FOR THE STUDY OF ADDICTION

Reduced nicotine content cigarettes, e-cigarettes and the cigarette end game

Neal L. Benowitz ✉, Eric C. Donny, Dorothy K. Hatsukami

Benowitz et al., Addiction, 2016

Public educational messaging is critical!

- **Nicotine is NOT being reduced because nicotine is intrinsically harmful, but rather because it sustains cigarette addiction.**
- **Reducing nicotine will make it easier to quit smoking**
- **If you wish to continue nicotine use, other less harmful forms of nicotine will remain available**

Conclusions

- Reducing the nicotine content of cigarette is likely to the reduce the addictiveness of cigarettes.
- The result would be preventing children from becoming addicted smokers and giving established smokers greater freedom to stop smoking when they decide to quit.
- Immediate rather than gradual nicotine reduction probably safest and most feasible

Conclusions

- **Electronic nicotine delivery systems would provide an attractive alternative to conventional cigarettes and would likely enhance public acceptance of a nicotine reduction policy.**
- **Possible long-term adverse health consequences of ENDS use, including primary nicotine addiction in youth remain a concern.**

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SPECIAL REPORT

Potential Public Health Effects of Reducing Nicotine Levels in Cigarettes in the United States

Benjamin J. Apelberg, Ph.D., M.H.S., Shari P. Feirman, Ph.D., Esther Salazar, Ph.D., Catherine G. Corey, M.S.P.H., Bridget K. Ambrose, Ph.D., M.P.H., Antonio Paredes, M.S., Elise Richman, M.P.H., Stephen J. Verzi, Ph.D., Eric D. Vugrin, Ph.D., Nancy S. Brodsky, Ph.D., and Brian L. Rostron, Ph.D., M.P.H.

Apelberg et al., NEJM, 2018

Apelberg Simulation of Effects of Mandatory Nicotine Reduction

- U.S. Population-based simulation model, 2016 to 2100
- Prediction: by year 2100 more than 33 million youth and young adults who would have become regular smokers would not start
- Prediction: 5 million smokers would quit within 1 year of implementation, and 13 million with 5 years

Preventive Medicine

The AMA proposal to mandate nicotine reduction in cigarettes: a simulation of the population health impacts

Tammy O. Tengs, Sc.D.,* Sajjad Ahmad, Ph.D., Jennifer M. Savage, B.A., Rebecca Moore, B.A., and Eric Gage, M.A.

Health Priorities Research Group, University of California, Irvine, CA, USA

Available online 8 July 2004

Tengs et al., Prev Med, 2005

Tengs Simulation of Population Health Impact of Mandatory Nicotine Reduction

Smoking prevalence likely to decline to 5%, with resultant gain of 137 million QALYs over 50 years

- **"Policy makers would be hard-pressed to identify another domestic public health intervention, short of historical sanitation efforts, that has offered this magnitude of benefit to the population."**

Tengs et al, *Prev Med* 2005, 40:170

New Zealand Action Plan for a Smokefree 2025

1. Ensure Maori leadership and decision making
2. Increase health promotion and community mobilization
3. Increase evidence-based stop smoking services
4. Reduce the addictiveness and appeal of smoke tobacco products (nicotine reduction)
5. Reduce the availability of smoked tobacco products (“smokefree generation”)

On vaping: ensure that smoked tobacco products are more regulated and less available than vaping products

72 public health organization support FDA mandated nicotine reduction

September 12, 2022

Submit questions via the **‘Q & A’ box**

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Physician Assistants: The National Commission on Certification of Physician Assistants (NCCPA) states that the *AMA PRA Category 1 Credit™* are acceptable for continuing medical education requirements for recertification.

California Pharmacists: The California Board of Pharmacy accepts as continuing professional education those courses that meet the standard of relevance to pharmacy practice and have been approved for *AMA PRA category 1 Credit™*. If you are a pharmacist in another state, you should check with your state board for approval of this credit.

California Psychologists: The California Board of Psychology recognizes and accepts for continuing education credit courses that are provided by entities approved by the Accreditation Council for Continuing Medical Education (ACCME). *AMA PRA Category 1 Credit*™ is acceptable to meeting the CE requirements for the California Board of Psychology. Providers in other states should check with their state boards for acceptance of CME credit.

California Behavioral Science Professionals: University of California, San Francisco School of Medicine (UCSF) is approved by the California Association of Marriage and Family Therapists to sponsor continuing education for behavioral health providers. UCSF maintains responsibility for this program/course and its content.

Course meets the qualifications for 1.0 hour of continuing education credit for **LMFTs, LCSWs, LPCCs, and/or LEPs** as required by the California Board of Behavioral Sciences. Provider # 64239.

Respiratory Therapists: This program has been approved for a maximum of 1.0 contact hour Continuing Respiratory Care Education (CRCE) credit by the American Association for Respiratory Care, 9425 N. MacArthur Blvd. Suite 100 Irving TX 75063, Course #189457000.

California Addiction Counselors: The UCSF Office of Continuing Medical Education is accredited by the **California Consortium of Addiction Professional and Programs (CCAPP)** to provide continuing education credit for California Addiction Counselors. UCSF designates this live, virtual activity, for a maximum of 1.0 CCAPP credit. Addiction counselors should claim only the credit commensurate with the extent of their participation in the activity. Provider number: 7-20-322-0724.

Free CME/CEUs will be available for all eligible California providers, who joined this live activity thanks to the support of the California Tobacco Control Program (CTCP)

For our California residents, SCLC offers regional trainings, online education opportunities, and technical assistance for behavioral health agencies, providers, and the clients they serve throughout the state of California.

For technical assistance please contact (877) 509-3786 or Jessica.Safier@ucsf.edu.

Visit CABHWI.ucsf.edu for more information

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- You will receive the following in our post webinar email:
  - ✓ Webinar recording
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  - ✓ Instructions on how to claim FREE CME/CEUs
  - ✓ Information on certificates of attendance
  - ✓ Other resources as needed

➢ All of this information will be posted to our website at https://SmokingCessationLeadership.ucsf.edu

SCLC next live webinar will be with **Dr. Brian King**, Director of the Center for Tobacco Products, FDA, on

- **Wednesday, March 22, 2023**
- **2:00 pm – 3:00 pm EST**

Contact us for free technical assistance

- **Visit** us online at **smokingcessationleadership.ucsf.edu**
- **Call** us toll-free at **877-509-3786**
- **Provide Feedback** - complete the evaluation, which you will see at the end of this webinar

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