

Presentation to the Seventh Annual CRAN Joint Council Meeting
May 13, 2020

Updates from NCI

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Outline of Presentation



NCI Cancer Center Cessation Initiative (C3i)



Surgeon General's Report on Smoking Cessation, January 2020



FDA Final Rule, Required Warnings for Cigarette Packages and Advertisements, March 2020

Cancer Statistics

- 1.8 million people will be diagnosed with cancer in the U.S. (2020)
- Smoking prevalence among cancer patients: 10-33% (self-report)
- Smoking **causes** cancer, **complicates** cancer treatment and **adds to cost** of oncology care
- Smoking cessation **improves the prognosis** of cancer patients
- Identifying and helping cancer patients who smoke to quit is not yet the standard of care in oncology

American Cancer Society. Cancer Facts & Figures 2020. Atlanta: American Cancer Society; 2020. U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.

2014 SGR Conclusions: Cancer Patients and Survivors

- evidence is sufficient...causal relationship between cigarette smoking and adverse health outcomes. Quitting smoking improves the prognosis of cancer patients.
- evidence is sufficient... causal relationship between cigarette smoking and increased all-cause mortality and cancer-specific mortality.
- evidence is sufficient...causal relationship between cigarette smoking and increased risk for second primary cancers known to be caused by cigarette smoking, such as lung cancer.
- evidence is suggestive (but not sufficient)...causal relationship between cigarette smoking and (1) the risk of recurrence, (2) poorer response to treatment, and (3) increased treatment-related toxicity

The NCI Cancer Centers Program

- Nationwide network of 71 diverse cancer centers performing laboratory, clinical, and population-based research in cancer
- Via P30 Cancer Center Support Grants, NCI funds research infrastructure in centers that meet rigorous standards for transdisciplinary, state-of-the art research on cancer prevention, diagnosis and treatment
- NCI “designation” recognizes achievement of centers, and enhances their ability to leverage additional resources for cancer research, education, and care
- Approximately 250,000 patients receive their cancer diagnosis at an NCI-designated Cancer Center. An even larger number of patients are treated for cancer at these centers each year

Addressing a Core Gap in Cancer Care (NEJM, 2019)



Perspective

Addressing a Core Gap in Cancer Care — The NCI Moonshot Program to Help Oncology Patients Stop Smoking

Robert T. Croyle, Ph.D., Glen D. Morgan, Ph.D., and Michael C. Fiore, M.D., M.P.H., M.B.A.

Despite making great progress in caring for people with cancer, the oncology community has often neglected to capitalize on a highly feasible, readily available, and cost-effective

strategy for increasing the success of cancer treatment and rates of recovery — smoking cessation. Effective smoking-cessation treatments can double or triple a smoker's chances of quitting successfully, and new treatment innovations that further boost quit rates continue to emerge. But such treatments are infrequently provided to patients as part of their cancer care.

Our failure to effectively address smoking in patients with cancer exacts steep costs. Evidence shows that continued smoking after a cancer diagnosis increases post-treatment mortality as well as the risk of a new primary cancer, the risk of cancer recurrence, and rates of adverse side effects from cancer treatment.^{1,2} Con-

versely, quitting smoking after a cancer diagnosis is associated with longer survival and a reduced risk of new cancers.³ The evidence is clear: for the approximately half of cancer patients who smoke at the time of their diagnosis, a cancer diagnosis signals an important and highly feasible opportunity to improve the effectiveness of cancer treatment and avert future cancers.

Despite recommendations (e.g., from the National Comprehensive Cancer Network) that all patients with cancer be offered effective treatment to help them quit smoking, such treatment is an often-neglected element of cancer care. For example, a 2009 survey of 58 National Cancer Institute (NCI)-designated clinical and

comprehensive cancer centers in the United States revealed that 27% offered no tobacco-use treatment services, only 62% routinely provided tobacco-education materials to patients, half reported having systems in place to identify which of their patients use tobacco, and less than half reported having a staff person dedicated to providing tobacco-treatment services or a commitment from center leadership to provide such services.³ Such inattention has had a predictable effect on the delivery of smoking-cessation interventions. Data show that just under half of cancer care providers consistently discuss cessation-medication options with their patients who smoke, and a similar proportion consistently treat their patients with cessation medications or refer them for treatment.⁴ Among people who have had cancer but continue to smoke, only about half report having received counseling or support to

“To address this cancer treatment gap, the National Cancer Institute (NCI), as part of the Cancer Moonshot, is launching a nationwide effort to help people **quit smoking while they are undergoing treatment for cancer.**”

To **“transform clinical cancer care so that, moving forward, evidence-based smoking cessation treatment is an integral and necessary component of care for every cancer patient who smokes.”**

Croyle RT, Morgan GD, Fiore MC. Addressing a Core Gap in Cancer Care - The NCI Moonshot Program to Help Oncology Patients Stop Smoking. *N Engl J Med.* 2019;380(6):512-515. doi:10.1056/NEJMp1813913

The Cancer Centers Cessation Initiative (C3I)

- NCI launched the Cancer Center Cessation Initiative, as part of the [NCI Cancer MoonshotSM program](#).
- Long-term goal: to help cancer centers build and implement sustainable tobacco cessation treatment programs to routinely address tobacco cessation with cancer patients.
- Cohort One: 22 centers (2017-2019)
- Cohort Two: 20 centers (2018-2020)
- Coordinating Center: University of Wisconsin Carbone Cancer Center - technical assistance and coordination.

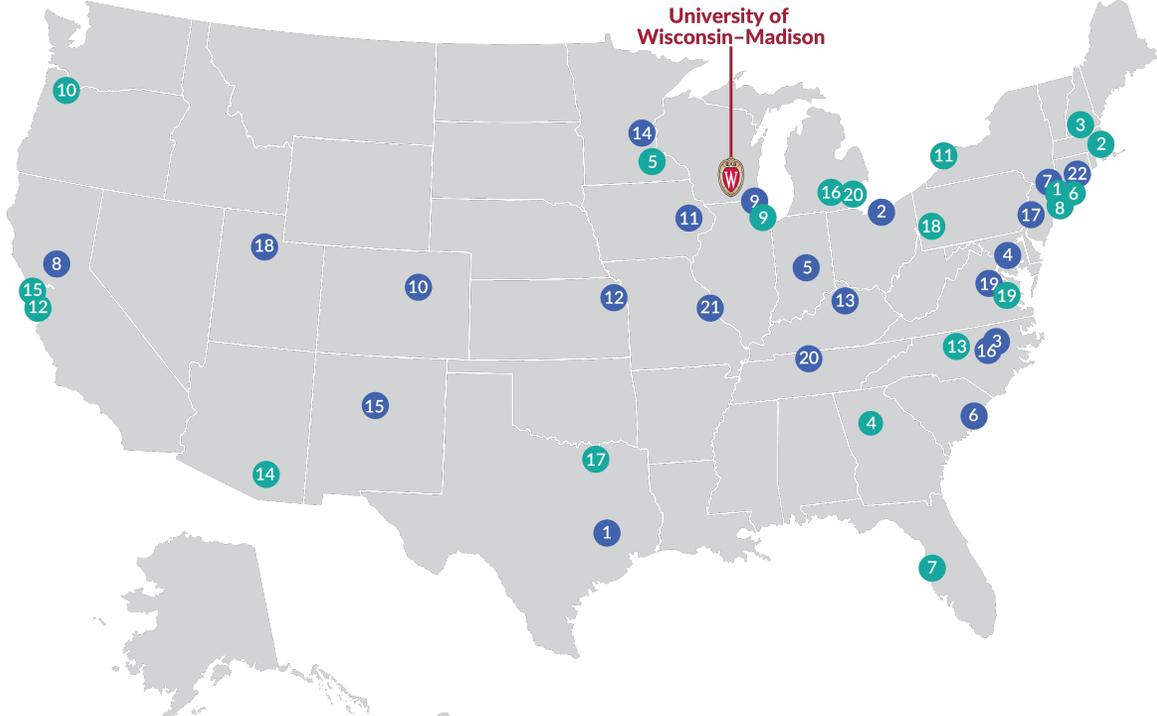


<https://cancercontrol.cancer.gov/brp/tcrb/key-initiatives.html>

C3I Site Activities to Enhance Delivery of Cessation Treatment

- Refine electronic medical records and clinical workflows to ensure the systematic identification and documentation of smokers and the routine delivery of evidence-based tobacco cessation treatment services
- Overcome patient, clinician, clinic, and health system barriers to providing tobacco cessation treatment services
- Achieve institutional buy-in that treating tobacco use is a component of organizational “Standard of Care”
- Create mechanisms to sustain tobacco cessation treatment services so that they continue beyond the funding period of the initiative

Cancer Center Cessation Initiative (C3I) Funded Centers



Cohort 1

- 1. Baylor College of Medicine
- 2. Case Western Reserve University
- 3. Duke University
- 4. Georgetown University
- 5. Indiana University
- 6. Medical University of South Carolina
- 7. New York University
- 8. University of California Davis
- 9. University of Chicago
- 10. University of Colorado
- 11. University of Iowa
- 12. University of Kansas
- 13. University of Kentucky
- 14. University of Minnesota
- 15. University of New Mexico
- 16. University of North Carolina at Chapel Hill
- 17. University of Pennsylvania
- 18. University of Utah
- 19. University of Virginia
- 20. Vanderbilt University
- 21. Washington University
- 22. Yale University

Cohort 2

- 1. Columbia University
- 2. Dana-Farber
- 3. Dartmouth College
- 4. Emory University
- 5. Mayo Clinic
- 6. Memorial Sloan Kettering
- 7. Moffitt
- 8. Mount Sinai
- 9. Northwestern University
- 10. Oregon Health and Sciences University
- 11. Roswell Park
- 12. Stanford University
- 13. Wake Forest University
- 14. University of Arizona
- 15. University of California San Francisco
- 16. University of Michigan
- 17. University of Texas Southwestern
- 18. UPMC Hillman
- 19. Virginia Commonwealth University
- 20. Wayne State University

Cancer Center Cessation Initiative (C3I) Leadership



Betsy Rolland, PhD



Michael Fiore, MD



Timothy Baker, PhD



Stephanie Land, PhD



**Steven
Bernstein, MD**



**Jamie
Ostroff, PhD**



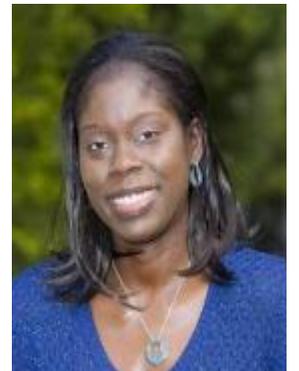
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Webb Hooper, PhD**





NIH NATIONAL CANCER INSTITUTE

Cancer Center Cessation Initiative

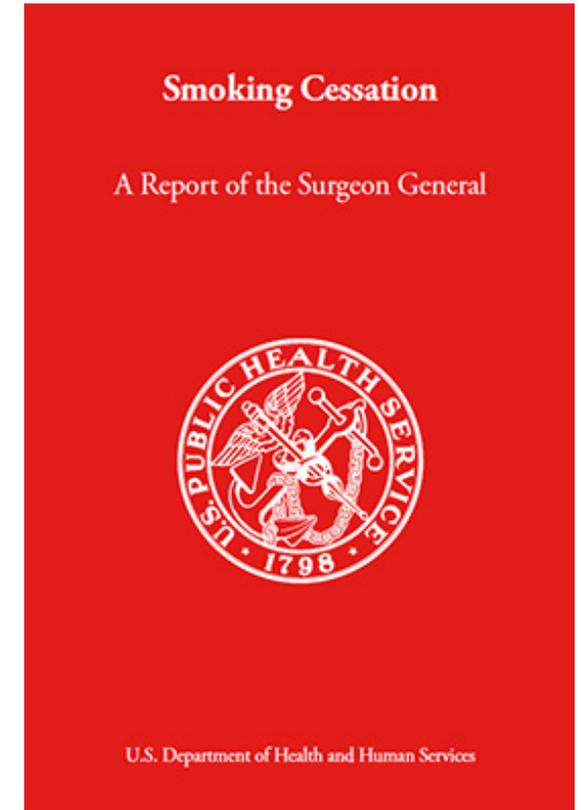
Implementing science-based
tobacco cessation treatment
into clinical practice

October 2018

Smoking Cessation: A Report of the Surgeon General, 2020

Goal: Update and expand the 1990 Surgeon General's Report, *The Health Benefits of Smoking Cessation*.

- The scientific literature has expanded greatly [since 1990] on the determinants and processes of smoking cessation, informing the development of interventions that promote cessation and help smokers quit.
- This knowledge and other major developments have **transformed the landscape of smoking cessation** in the United States.
- This report summarizes new knowledge and reviews patterns and trends of:
 - smoking cessation;
 - biologic mechanisms;
 - health benefits;
 - overall morbidity, mortality;
 - economic benefits of cessation;
 - Interventions and policies that promote smoking cessation.



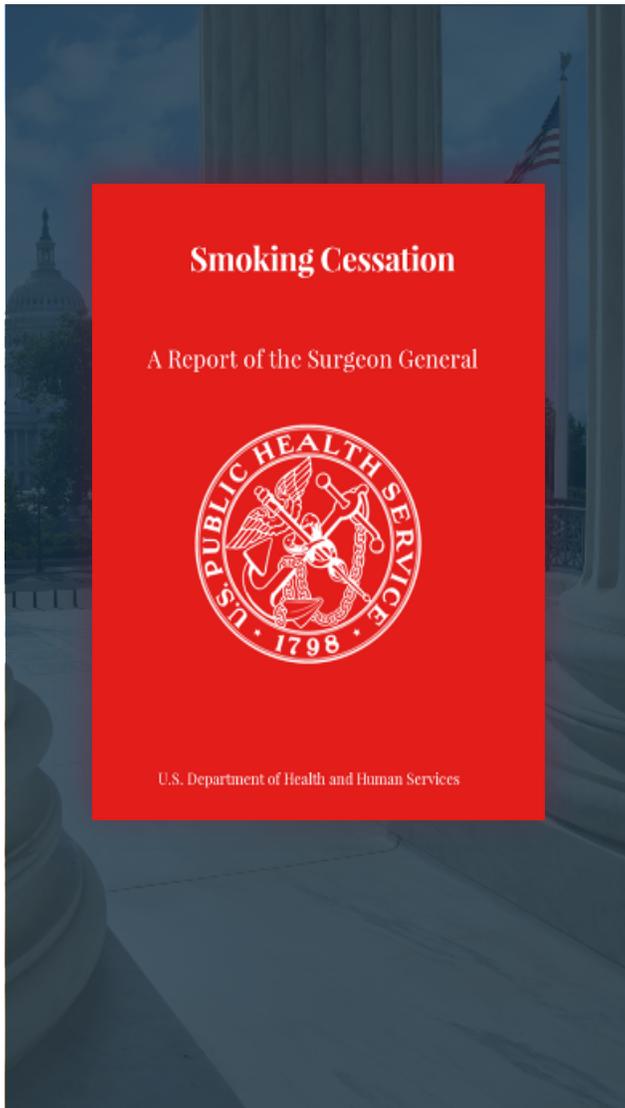
10 MAJOR CONCLUSIONS

1. Smoking cessation is beneficial at any age. Smoking cessation improves health status and enhances quality of life.

2. Smoking cessation reduces the risk of premature death and can add as much as a **decade** to life expectancy.

3. Smoking places a substantial financial burden on smokers, healthcare systems, and society. Smoking **cessation reduces this burden**, including smoking-attributable healthcare expenditures.

4. Smoking cessation reduces risk for many adverse health effects, including reproductive health outcomes, cardiovascular diseases, chronic obstructive pulmonary disease, and cancer. **Quitting smoking is also beneficial to those who have been diagnosed with heart disease and chronic obstructive pulmonary disease.**

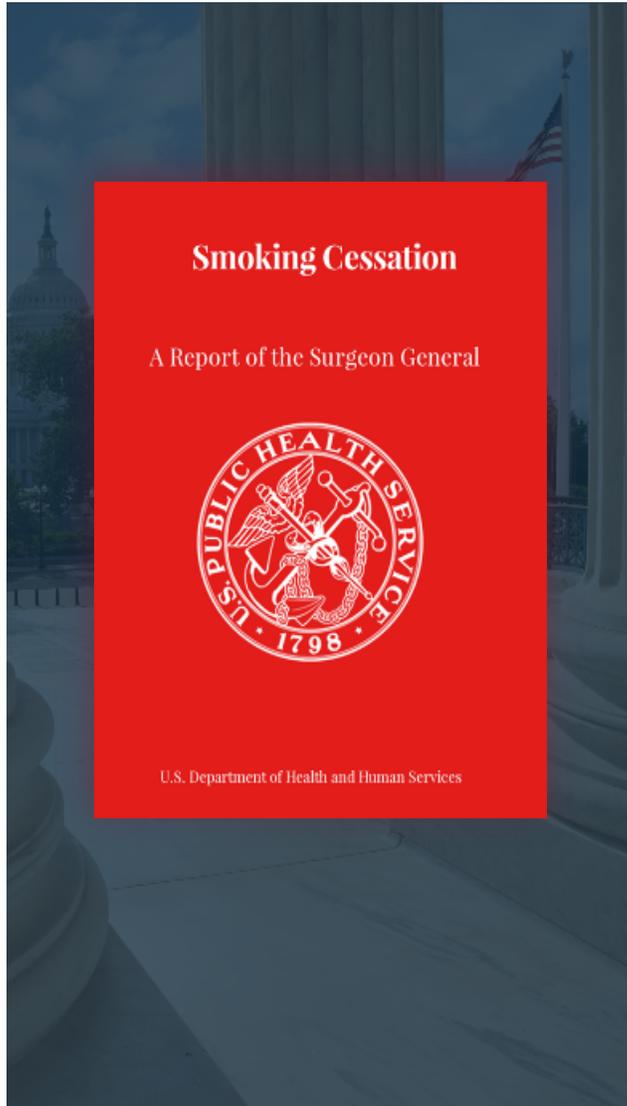


10 MAJOR CONCLUSIONS

5. More than three out of five U.S. adults who have ever smoked cigarettes have quit. Although a majority of cigarette smokers make a quit attempt each year, **less than one-third use cessation medications approved by the U.S. Food and Drug Administration (FDA) or behavioral counseling to support quit attempts.**

6. Considerable disparities exist in the prevalence of smoking across the U.S. population, with higher prevalence in some subgroups. Similarly, the prevalence of key indicators of smoking cessation—quit attempts, receiving advice to quit from a health professional, and using cessation therapies—also varies across the population, with lower prevalence in some subgroups.

7. Smoking cessation medications approved by the U.S. Food and Drug Administration (FDA) and behavioral counseling are cost-effective cessation strategies. Cessation medications approved by the FDA and behavioral counseling increase the likelihood of successfully quitting smoking, particularly when used in combination. Using combinations of nicotine replacement therapies can further increase the likelihood of quitting.

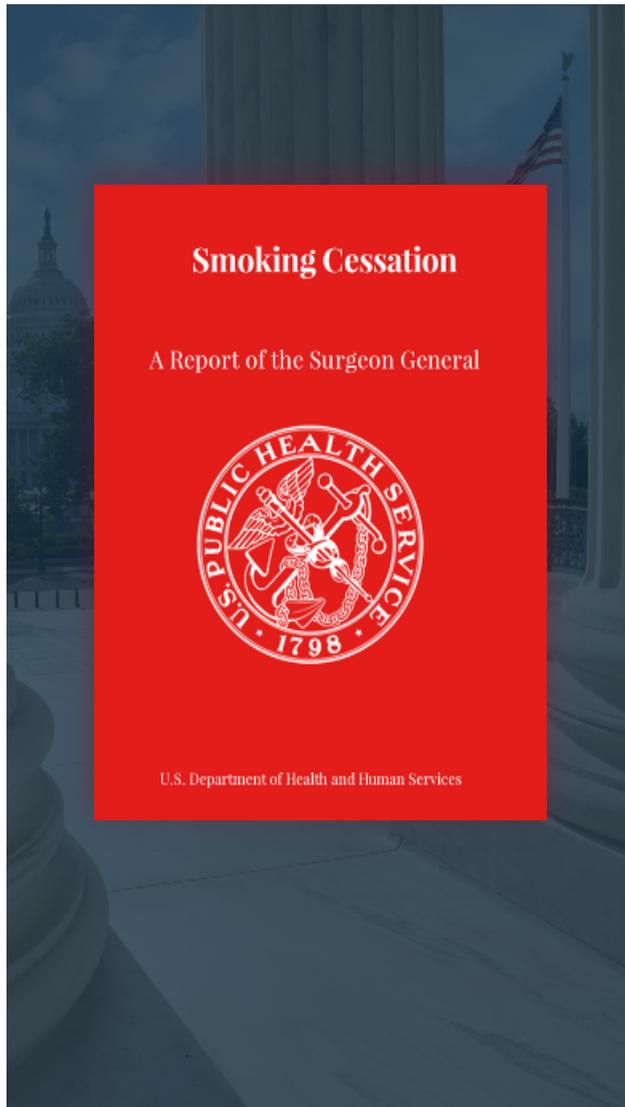


10 MAJOR CONCLUSIONS

8. Insurance coverage for smoking cessation treatment that is **comprehensive, barrier-free, and widely promoted** increases the use of these treatment services, **leads to higher rates of successful quitting, and is cost-effective.**

9. E-cigarettes, a continually changing and heterogeneous group of products, are used in a variety of ways. Consequently, it is difficult to make generalizations about efficacy for cessation based on clinical trials involving a particular e-cigarette, and **there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation.**

10. Smoking cessation can be increased by **raising the price of cigarettes, adopting comprehensive smokefree policies, implementing mass media campaigns, requiring pictorial health warnings, and maintaining comprehensive statewide tobacco control programs.**



FDA Final Rule: Required Warnings for Cigarette Packages and Advertisements, March 2020

2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) requires FDA to issue regulations requiring **color graphics** depicting the negative health consequences of smoking to accompany new **textual warning** label statements.

The final rule specifies the **11 new** textual warning label statements and accompanying color graphics. Rule take effect: June 18, 2021 (15 months)

FDA determined that the public holds misperceptions about the health risks caused by smoking and that textual warning statements focused on less-known health consequences of smoking paired with concordant color graphics will promote greater public understanding of the risks associated with cigarette smoking, especially given that the existing Surgeon General’s warnings currently used in the United States go unnoticed and are **effectively “invisible.”**

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 53 (March 18, 2020)

U.S. Food and Drug Administration. FDA Proposes New Health Warnings for Cigarette Packs and Ads.

<https://www.fda.gov/tobacco-products/ctp-newsroom/fda-proposes-new-health-warnings-cigarette-packs-and-ads>. Updated 1 May 2020. Accessed 5 May 2020.

FDA Final Rule: Required Warnings for Cigarette Packages and Advertisements, March 2020

United States



Mexico



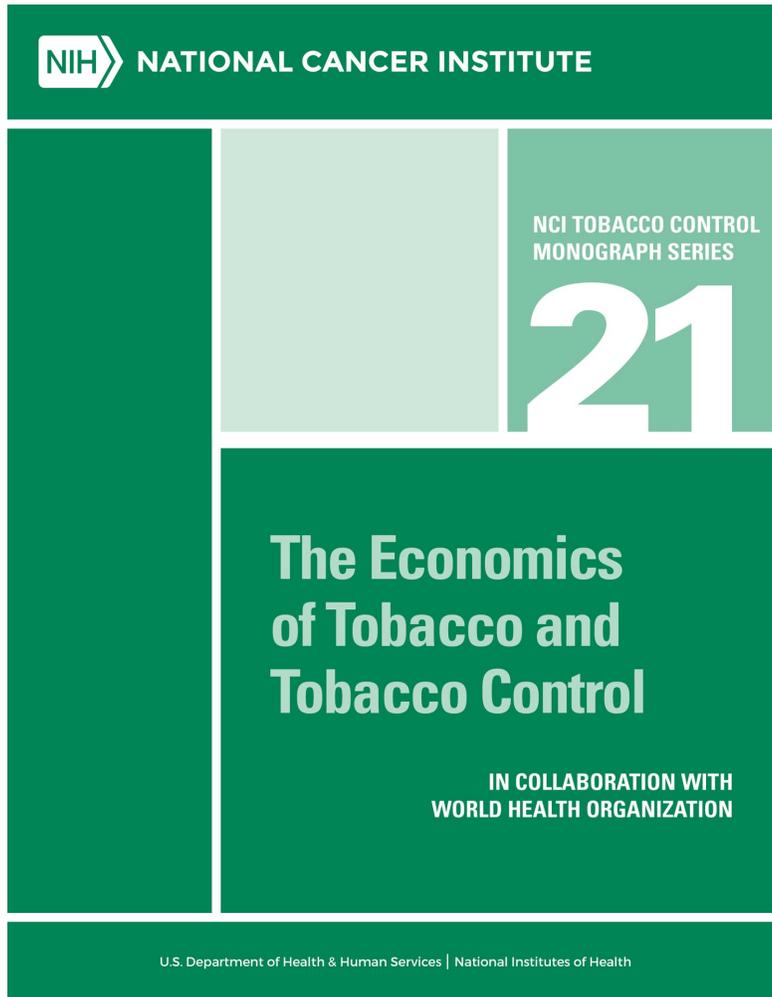
Canada



Tobacco Products; Required Warnings for Cigarette Packages and Advertisements, 85 Fed. Reg. 53 (March 18, 2020)
 U.S. Food and Drug Administration. FDA Proposes New Health Warnings for Cigarette Packs and Ads.
<https://www.fda.gov/tobacco-products/ctp-newsroom/fda-proposes-new-health-warnings-cigarette-packs-and-ads>. Updated 1 May 2020.

Canadian Cancer Society, Cigarette Package Health Warnings: International Status Report, Fifth Edition, October 2016.

Strong Science Base Supports Pictorial Warnings



- “Large pictorial health warning labels on tobacco packages are effective in increasing smokers’ knowledge, stimulating their interest in quitting, and reducing smoking prevalence. These warnings may be an especially effective tool to inform children and youth and low literacy populations about the health consequences of smoking.” (NCI-WHO Monograph 21)
- “Article 11 of the WHO Framework Convention on Tobacco Control (WHO FCTC) requires Parties to the Convention to implement large, rotating health warnings on all tobacco product packaging and labelling. Pictorial health warnings on tobacco packages are a cost-effective means to increase public awareness about the dangers of tobacco use.”

<https://www.who.int/tobacco/healthwarningsdatabase/en>

WARNING:
Smoking causes
type 2 diabetes,
which raises
blood sugar.



WARNING:
Smoking causes
cataracts, which
can lead to
blindness.



WARNING:
Smoking can cause
heart disease
and strokes by
clogging arteries.



New Health Warnings with Color Graphics

1. WARNING: Tobacco smoke can harm your children.
2. WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
3. WARNING: Smoking causes **type 2 diabetes**, which raises blood sugar.
4. WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
5. WARNING: Smoking **causes cataracts**, which can lead to blindness.
6. WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
7. WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
8. WARNING: Smoking causes head and neck cancer.
9. WARNING: Smoking can cause **heart disease and strokes** by clogging arteries.
10. WARNING: Smoking during pregnancy stunts fetal growth.
11. WARNING: Smoking causes COPD, a lung disease that can be fatal.

1. U.S. Food and Drug Administration. Cigarette health warning design files and technical specifications. Available from: <https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-health-warning-design-files-and-technical-specifications>. Updated 18 March 2020. Accessed 8 May 2020.

2. 1. U.S. Food and Drug Administration. Cigarette Health Warning Design Files and Technical Specifications. <https://www.fda.gov/tobacco-products/labeling-and-warning-statements-tobacco-products/cigarette-health-warning-design-files-and-technical-specifications>. Updated 18 March 2020. Accessed 5 May 2020.

Plain (Standard) Packaging

“Strip back the glamour and glossy packaging that contain tobacco products, and what is left? A product that kills almost 6 million people every year. Tobacco packaging is a form of advertising and promotion that often misleads consumers and serves to hide the deadly reality of tobacco use. ... plain packaging works.”

WHO Director-General Dr Margaret Chan, World No Tobacco Day, May 31, 2016



1. Tobacco Labelling Resource Centre. Plain Packaging Images [cited 8 May 2020]. Available from: <https://tobaccolabels.ca/plain-pack-images/>
2. Canadian Cancer Society, Cigarette Package Health Warnings: International Status Report, Fifth Edition, October 2016.

Global Momentum Towards Plain (Standard) Packaging

- Australia: implemented 2012.
- 14 countries have now finalized requirements for plain packaging. (Australia, New Zealand, United Kingdom, France, Ireland, Norway, Hungary, Slovenia, Turkey, Uruguay, Thailand, Saudi Arabia, Israel and Canada).
- “Plain (standardized) packaging (i.e., devoid of logos, stylized fonts, colors, designs or images, or any additional descriptive language) reduces the appeal of tobacco products, enhances the salience of health warnings, minimizes consumers’ misunderstanding of the harms of tobacco, and has contributed to a decline in tobacco use in Australia, the first country to implement plain packaging.”



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